betacontrol of America

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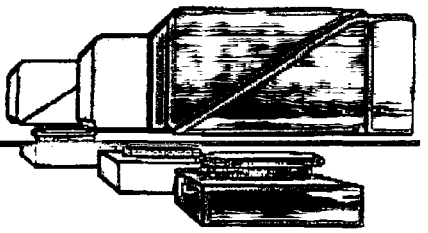

August 27, 2004

NRC
ATTN.: Tomas Herrera
11555 Rockville
Rockville, MD 20852

Subject: Additional information on amendment for transmission gauge NR-122-D-101-B

Dear Tomas,

This letter is in response to your request of additional information from August 2, 2004, for the amendment to the registration certificate NR-0122-D-101-B.

I am pleased to help you in this matter. I will answer your questions in the way they appear in your letter.

The new source housing MK 1.0 is developed and build in appliances with the 'quality management system' ISO 9001:2000. A copy of this certification is part of the attachment.

I thank you for assisting me in this matter.

If you have any questions, please feel free to call me.

Best regards,

Markus Hannig
Manager
Sales & Service

betacontrol of America

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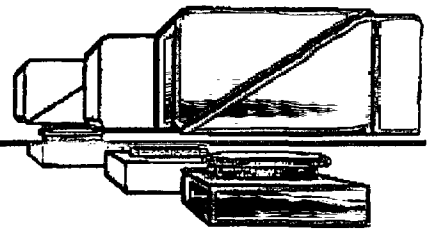

Introduction

Section 1 of this letter contains the specifications according to the following topics. Reference numbers are used to refer to the drawings of section 2.

1. Description / Construction:
2. Conditions of Use
3. Prototype Testing
4. Radiation Profiles
5. Labels

Section 2 contains the drawings and the illustrations of the old and the new version of the transmission gauge MK 1.0 and of related parts. It contains a drawing list with a description and the reference numbers, which gives an overview of the drawings and the illustrations. Section 2 includes the following drawings:

1. O-Frame
2. Sensor MK 1.0 new Version
3. Sensor MK 1.0 old Version
4. Source housing MK 1.0 new Version detail drawing
5. Source housing MK 1.0 new Version service instructions
6. Source housing MK 1.0 old Version
7. Label with address information for MK 1.0 new Version
8. Label with source information for MK 1.0 new Version
9. Label with maintenance information for MK 1.0 new Version
10. Labels for source housing MK 1.0 old Version
11. Shielding Kr-85 for MK 1.0 new Version
12. Shielding Sr-90 for MK 1.0 new Version
13. Shielding Am-241 / Pm-147 for MK 1.0 new Version
14. Isodose curves for Kr-85, 500 millicuries (18.5 GBq) for MK 1.0 new Version unshielded
15. Isodose curves for Kr-85, 500 millicuries (18.5 GBq) for MK 1.0 new Version shielded
16. Isodose curves for Sr-90, 50 millicuries (1.85 GBq) for MK 1.0 new Version unshielded
17. Isodose curves for Sr-90, 50 millicuries (1.85 GBq) for MK 1.0 new Version shielded
18. Isodose curves for Pm-147, 50 millicuries (1.85 GBq) for MK 1.0 new Version unshielded
19. Isodose curves for Pm-147, 50 millicuries (1.85 GBq) for MK 1.0 new Version shielded

Section 3 is an appendix. It consists of the betacontrol ISO 9001:2000 certification, a description of the used source models, a description of the source manufacturers quality control measures and a description of the source manufacturers source safety standards.

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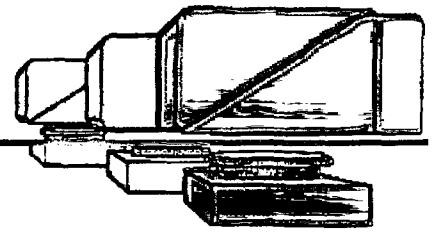


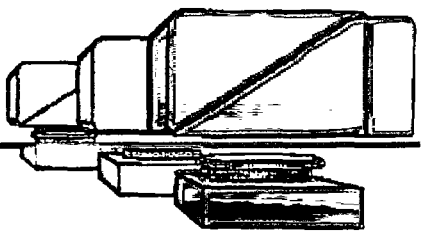
Section 1

1. Description / Construction:

1.1 Table of Differences between New and Old Version

The list below shows the differences between the new and the old Version of the source housing MK 1.0, which is also denoted to "BC MK 1.0" (betacontrol MK 1.0). The described modifications do not change the application or function of the new source housing MK 1.0 compared to the old source housing MK 1.0. These modifications are improving the shielding of the source and the save handling of the source housing MK 1.0 and helps us to follow ALARA (As Low As is Reasonably Achievable) in take risks for the operators and service technicians working with our source housing MK 1.0.

MK 1.0 New Source Housing	MK 1.0 Old Source Housing
With the new source housing the operator has additional information of the shutter position. A window gives access to a color indication which mechanically indicates the shutter position. The color indicator is red if the shutter is open and it is green when the shutter is closed (see drawing **S04-41021**). The color indicator increases the safety and the user friendliness.	There is no window and no mechanical indication for the shutter position. The warning lights on the top of the scanner are the only visual indication for the shutter position.
The plugs X16.1 are smaller.	The plugs X16.1 are bigger.
The collimator plate is smaller because the size of the shielding foil of the gap was reduced (see drawing **S04-41021**).	The collimator plate is much bigger (see drawing **700-3241/3**).
The shielding foil is smaller which minimized the possible damage of the shielding foil (see drawing **S04-41021**). The reduction of the shielding foil size enhances the reliability of this part.	The shielding foil is much bigger (see drawing **700-3241/3**). The shielding foil has its main function in protecting the inside of the source housing from dust.
The shielding foil is mounted to a sliding shoe what makes the replacement faster and reduces the exposure. It is not necessary anymore to take the source housing off the gauge to replace the shielding foil (see **Service instructions**).	The shielding foil is stretched over the collimator plate by a ring. A replacement of the dustcover is time consuming and the technician is exposed to a certain amount of radiation during this service. It is necessary to take the source housing off the gauge to replace the shielding foil (see drawing **700-3241/3**).
The Kr-85 sources have a higher impacted resistivity. For more information see chapter 3.1.1 Operational History of the Model "MK 1.0 / New Version.	The Kr-85 sources are more sensitive for impacts. For more information see chapter 3.1.1 Operational History of the Model " MK 1.0 / New Version.



MK 1.0 New Source Housing	MK 1.0 Old Source Housing
The feeding assistance is a part of the source housing. The feeding assistance makes it easier to feed the measured product trough the gap (see drawing **S01-103-001-3**).	The feeding assistance is an additional feature and was only supplied when customers ordered it.
A transport locking screw keeps the shutter rigidly locked during the transport (see drawing **S04-41021**).	There is no locking device. The source shutter is closed during transport, but not locked.
The bottom part of the source is now covered with a steel shield and an additional lead shield (see drawing **S04-41021**).	No steel shield and no lead shield for the bottom part of the source.

1.2 Distinction between Old and New Version of the MK 1.0

The new version of the transmission gauge MK 1.0 is distinguished from the old Version of the MK 1.0 by the serial number. The devices of the new version of the MK 1.0 are described by four digit serial numbers of 1001 and above. The devices of the old version of the MK 1.0 are described by serial numbers below 999 with three or less than three digits.

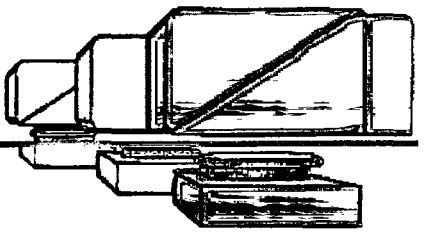
1.3 Units

All units of the drawings are in millimeters, if not otherwise indicted.

2. Conditions of Use:

The radionuclide and the maximum activity levels used by the MK 1.0 will remain the same:

Isotope	Maximum Activity
Sr-90	1.85 GBq / 50 millicuries
Kr-85	18.5 GBq / 60 millicuries
Kr-85	18.5 GBq / 500 millicuries
Am-241	11.1 GBq / 300 millicuries
Pr-147	1.85 GBq / 50 millicuries



3. Prototype Testing:

3.1 Prototype Testing

The changes from the old Version of the transmission gauge MK 1.0 to the new version are minor changes based on a redesign in order to enhance the safety of the gauge and to reduce the external radiation. Thus for the evaluation of the prototype testing one should above all consider the operational history, the high reliability and the safe operation of the equivalent and similar old version of the transmission gauge MK 1.0. The following investigations about the integrity of the new version of the source housing MK 1.0 are based on prototype testing, on experience with the operational history of the new and the old version of the MK 1.0 source housing and on engineering analysis.

3.1.1 Operational History of the Model MK 1.0

An old version of the transmission gauge MK 1.0 was distributed by the Albrecht Bäumer Kg from June 1985 to 1993, at which time the name changed to betacontrol. Bäumer of America, Inc. relied on the ANSI-N542 classification of the sources and the past use of the device in Europe and the USA in industrial environments since 1985 without operational problems causing unnecessary radiation exposure to users.

Additionally, Bäumer of America, Inc., provided the following ANSI-N538 Classifications for the device:

1. with source Kr-85, 60 mCi (2.2 GBq), 0.37 in (9.5 mm) gap: ANSI-33-355-775-RI

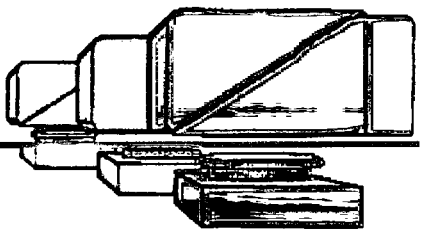
2. with source Kr-85, 150 mCi (5.6 GBq), 0.37 in (9.5 mm) gap: ANSI-33-245-665-RI

3. with source Sr-90, 10 mCi id.37 GBq), 1.3 in (33 mm) gap: ANSI-33-344-885-RI

4. with source Am-241, 300 mCi (11.1 GBq), 13.2 in (335 mm) gap: ANSI-33-564-985-RI

5. with source Am-241, 300 mCi (11.1 GBq), 1.97 in (50 mm) gap: ANSI-33-775-985-RI

These devices were distributed under a specific license by Bäumer of America, Inc., from 1985 to June, 1993, at which time the name was changed to betacontrol. Bäumer of America Inc., stated that no incidents of failure of the device causing a radiological hazard had been reported as of July 8, 1992.



Several hundred systems of the old version of the MK 1.0 were delivered and installed by betacontrol at different facilities. They have run several years in normal use without any operational problems causing unnecessary radiation exposure to users.

Several identical systems of the transmission gauge MK 1.0 with the new version of the source housing were installed at different facilities. They have run several months in normal use without any operational problems causing unnecessary radiation exposure to users. During the time from 1992 to now we are aware of no problems or failures of any safety components or loss of source containment as well for the old version of the MK 1.0 as for the new version of the MK 1.0, as of August 26, 2004.

For the new version of the MK 1.0 betacontrol carried out reliability tests for the source housing and the source shutter. These tests have been carried out successfully with 10 000 shutter cycles, at a temperature of -20°C (-4°F) and several times at temperatures of 20°C (68°F), and 60°C (140°F).

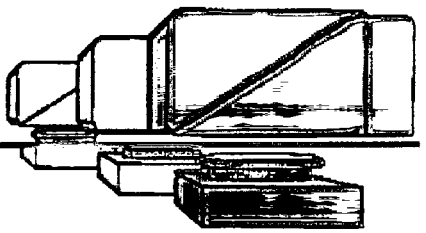
The radioactive sealed source models, which are used in the new version of the transmission gauge MK 1.0 were already used by the old version of the MK 1.0 according to the registration certificate no. NR-0122-D-101-B. The source models are listed in the following table:

No	Isotope	Source Manufacturer	IDNS Model No.	ANSI/ISO Old Version	ANSI/ISO New Version
1	Sr-90	AEA Technology plc	SIF.D1	C64343	C64343
2	Kr-85	AEA Technology plc	KAC.D1	C33232	C33332
3	Kr-85	AEA Technology plc	KAC.D3	C43232	C43332
4	Am-241	AEA Technology plc	AMC.17	C64444	C64444
5	Pr-147	AEA Technology plc	PHC.C1	C33222	C33222

The source models are ANSI/ISO classified according to ISO 2919:1999. The specifications of the source models are given in the appendix no 2 – no 6 in section 3 of this writing. The production of the sources by AEA Technology plc (former Amersham Corp.) is subject to a high degree of quality assurance (cf. appendix no 7 – no 8 in section 3) and is ANSI/ISO 9001-2000 certified. For more information on the source safety of our sources from AEA Technology plc see appendix no 9 – no 12 in section 3.

3.1.2 Comparison to the Similar and Equivalent Model "MK 1.0 / old version"

Our investigations focus on the maintenance of the integrity of the device and the following specifications focus on the weakest part of the new version of the MK 1.0 source housing. The source is positioned above the center of the source housing and fixed to the top of the source housing. In terms of shock stress (e.g. impact or puncture) the collimator plate and the source shutter (also denoted shielding bracket) protect the source. The source housing of the new version and the old version of the MK 1.0 both include a 6 mm thick source shutter and a 6 mm thick Collimator plate (see drawing **S04-41021** for the new version and **700-3241/3** for the old version). However, in terms of mechanical robustness the shutter locking system and the improved steel



and lead enclosure of the source (see drawing **S04-41021, S04-52001-3, S04-52005-3, S04-52007-3,** for the new version and **700-3241/3** for the old version) are significant advances of the new version. Furthermore the improved steel and lead enclosure of the source works as an effective shielding.

There is a difference in the ANSI/ISO classification (cf. source table in chapter 3.1.1) between the sources which are used in the new version of the MK 1.0 and the sources which have been used in the old version of the MK 1.0: The Kr-85 sources no 2 and no 3 (KAC.D1 and KAC.D3) are now classified for a higher impact. The sources which have been used in the old MK 1.0 version were tested for 50 g at 1 m and the sources which are used in the new MK 1.0 version are tested for 200 g at 1 m. However, the model of the source remains the same.

3.2 Conditions for Use, Handling, Storage and Transport

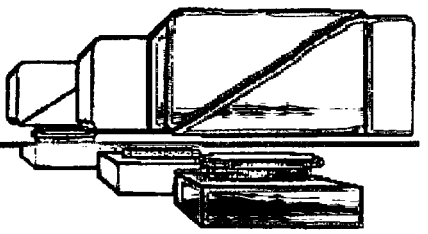
The determination of the specifications, which are required to maintain the integrity of the device highly depends on the specific situation of use, handling, storage and transport:

- The **transport** of the source housing (new version and old version of the MK 1.0) is always carried out in Type-A containers. During transport the external stress (temperature, shock, vibration and corrosion) is moderated by the container, whereas the specification in the following table does not include the moderating effect of the container and the packaging. In this respect the table describes the worst case situation. We ordered a laboratory test of a typical type-A container and got the following container data:

Size:	584 mm x 384 mm x 458 mm.
Bursting strength:	2027 kPa
Dynamic stacking strength:	6591 N
Static stacking strength (24 hr):	4700 N
Shock puncture strength:	8,34 Nm

- During **transport, storage** and **handling** of the new version and the old version of the MK 1.0 source housing the source shutter, which shields and physically protects the radioactive source, is closed due to the lack of operating voltage. Furthermore during **transport** and **storage** the source shutter is locked by a locking mechanism with a locking screw.

- The regular **use** of the new version of the MK 1.0 source housing as well as the use of the old Version of the MK 1.0 is always in the following configuration: The source unit (also denoted source housing) (see drawing **S01-103-001-3** for the new Version and **700-103-001-3** for the old Version) is mounted together with the detector unit in the robust and rigid o-frame (see drawing **700-010-590/2**). This configuration with the detector just above the source housing is enforced by a synchronous belt drive, unless a serious accident causes the destruction of system parts. The measuring product is in the gap between the source unit and the detector unit. The geometrical arrangement of this configuration protects the radioactive source, which is positioned just above the center of the source unit, from a



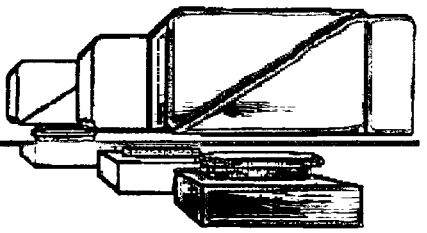
variety of puncture and impact influences: The position of the o-frame and the detector unit above the source unit, with a gap in between, protects the source from falling parts, which may hit or puncture the source unit. The specification in the following table does not include this protection by the configuration of regular use. In this respect the table describes the worst case situation, e. g. in an accident with a broken synchronous belt drive and a irregular displacement of source housing and detector unit.

- The **handling** of the new Version of the MK 1.0 source housing as well as the **handling** of the old Version of the MK 1.0 is always carried out without operating voltage. Therefore the source shutter is closed in this case.

	Use (open shutter)	Handling (closed shutter)	Storage (locked shutter)	Transport (locked shutter)
Minimum Temperature	0°C[1] 32°F[1] -40°C (20 min) -40°F (20 min)	0°C 32°F -40°C (20 min) -40°F (20 min)	-20°C -4°F -40°C (20 min) -40°F (20 min)	-20°C -4°F -40°C (20 min) -40°F (20 min)
Maximum Temperature	50°C[2] 122°F[2] 80°C (1 hr) 176°F (1 hr)	50°C 122°F 80°C (1 hr) 176°F (1 hr)	60°C 140°F 80°C (1 hr) 176°F (1 hr)	60°C 140°F 80°C (1 hr) 176°F (1 hr)
Vibration	ranges from mild to zero	ranges from mild to zero	ranges from mild to zero	ranges from mild to zero
Shock (impact)	> 200 g x 1m (50 g x 1 m [3])	> 200 g x 1 m	> 200 g x 1 m	> 200 g x 1 m
Shock (puncture)	> 200 g x 1 m (1 g x 1 m [4])	> 200 g x 1 m	> 200 g x 1 m	> 200 g x 1 m
Corrosion	Industrial atmospheres, no strong corrosives, humidity: max 95% (no condensation)	industrial atmospheres, no strong corrosives, humidity: max 95% (no condensation)	industrial atmospheres, no strong corrosives, humidity: max 95% (no condensation)	industrial atmospheres, no strong corrosives, humidity: max 95% (no condensation)

3.2.1 Minimum and Maximum Temperature

The range between the permanent minimum operating temperature (1) and the permanent maximum operating temperature (2) of the transmission gauge MK 1.0 and the peripheral electronics guarantees the functionality of all system components. The temperature range which guarantees the integrity of the MK 1.0 source housing is given by the temperature range of the sealed radionuclide sources. The sources (cf. 3.1.1 and appendix no 2 – no 6 in section 3) are classified and tested in a temperature range of at least –40°C to 80°C (-40°F to 176°F) according to ISO 2919 and DIN 25426.



3.2.2 Vibration

A shutter locking screw was introduced into the new MK 1.0 source housing as compared to the old MK 1.0 source housing. This mechanism allows the robust locking of the source shutter shield in the case of non operation, storage and transport. This improvement enhances the safety of the MK 1.0 source housing in case of shock and vibration of high magnitude.

3.2.3 Shock

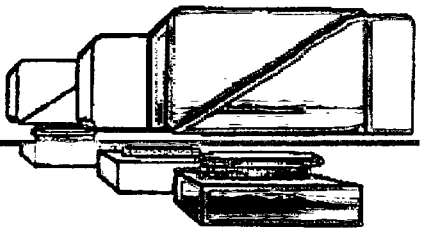
For the determination of the stress in form of shock we distinguish between impact shock and puncture shock according to ISO 2919-1999 and DIN 25426. The specifications given in this Chapter are based on the description of the test methods "impact test" and "puncture test" of ISO 2919-1999 and on engineering analysis.

3.2.3.1 Impact Shock

The impact shock test according to ISO 2919-1999 is defined by a hammer of 25 mm external diameter, which drops from a height of 1m on the most vulnerable area of the source. The most vulnerable area of the source is the measuring gap at the top of the source housing in the collimator plate. The hammer does not fit into the measuring gap, since the external diameter of the hammer is bigger than the size of the measuring gap.
Thus the impact of the hammer does not hit the source directly, but it will hit the collimator plate, which is 6 mm thick and rigidly attached to the robust sides of the source housing (cf. drawing **S04-41021**). The specification of the acceptable impact shock due to engineering analysis will be at least 200 g x 1m in this case. In this respect there is no difference between use, handling, storage and transport. However, in the situation of handling, storage and transport the source shutter is closed or even locked, which results in an additional protection. The impact shock test according to ISO 2919-1999 may lead to the result, that the acceptable impact shock is way higher than 200 g x 1m, but this test was not yet carried out by betacontrol.
(3): However, in exceptional (see chapter 3.2 "The regular **use**") situations with an impact of a very small body the test according to ISO 2919-1999 may not be sufficient and the impact classification of the source (50 g x 1m) may apply.

3.2.3.2 Puncture Shock

The puncture shock test according to ISO 2919-1999 is defined by a hammer with a pin of an external height of 6 mm and a diameter of 3 mm, which drops from a height of 1 m on the most vulnerable area of the source. The most vulnerable area of the source is the measuring gap at the top of the source housing in the collimator plate. However, the size of the hammer is not defined in ISO 2919-1999. Therefore we assume the specification for the size of hammer to be of 25 mm external diameter, which is the same as for the impact shock test. The hammer does not fit into the measuring gap, since the external diameter of the hammer is bigger than the size of the measuring gap.



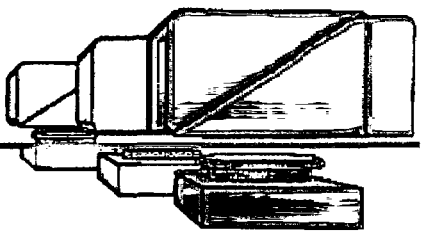
However, the 6 mm long pin will fit into the measuring gap and intrude as deep, as the thickness of the collimator plate. As long as the bending of the 6 mm thick collimator plate is below 1 mm, the impact will not reach the shield of the radioactive source. If the bending of the 6 mm thick collimator plate is above 1 mm, the impact will reach the source shutter in case of a closed or locked source shutter. In this case, the impact will not reach the source directly, it will reach only the shield of the radioactive source via the source shutter. If the bending of the 6 mm thick collimator plate is above 1 mm in case of an open source shutter, the impact will not reach the source shutter directly, nor the shield of the radioactive source directly nor the source directly.

Thus the impact of the hammer does not hit the source directly, but in all considered cases it will hit the collimator plate, which is 6 mm thick and rigidly attached to the sides of the source housing (cf. drawing **S04-41021**). The specification of the acceptable impact shock due to engineering analysis will be at least 200 g x 1m in this case. In this respect there is no difference between use, handling, storage and transport. However, in the situation of handling, storage and transport the source shutter is closed or even locked, which results in an additional protection. The impact shock test according to ISO 2919-1999 may lead to the result, that the acceptable impact shock is way higher than 200 g x 1m, but this test was not yet carried out by betacontrol.

(4): However in exceptional (see chapter 3.2 "The regular **use**") situations with an impact of a very small and long body the test according to ISO 2919-1999 may not be sufficient and the puncture classification of the source (1 g x 1m) may apply.

3.2.3.3 Corrosion

In betcontrol's long term experience with the industrial application of the old MK 1.0 transmission gauge corrosion never occurred as a problem. The materials of the transmission gauge did not show corrosion in industrial applications, during transport und proper storage. The old version and the new version use the same materials and source models, therefore we expect the same corrosion resistivity for the new Version of the MK 1.0 transmission gauge.



4. Radiation Profiles:

4.1 Radiation Gauge and Calibration

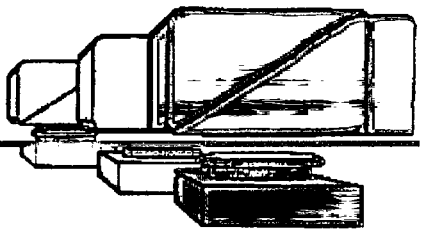
The radiation profiles of the new Version of the transmission gauge MK 1.0 were measured with a babyline 31 radiation gauge, Type E433A. The manufacturer of this radiation gauge is Fa. Nardeaux, 37600 Loches, France and the manufacturer identification is 2683. This radiation gauge was calibrated on the 10th of June 2002 and this calibration is valid until the 31st of December 2004.

4.2 Radiation Profiles in Shielded and Unshielded Positions

The radiation profiles of the new version of the MK 1.0 source housing were measured according to DIN VDE 0412-1. The measurements have been carried out with the radionuclides, which are going to be used in the MK 1.0 for the shielded and the unshielded positions each. The radionuclides used in the measurements are Kr-85 with an activity of 9.9 GBq, Sr-90 with an activity of 0.37 GBq and Pm-147 with an activity of 18.5 GBq. The measurement activities of the radionuclides differ from the maximum activities to be used in the MK 1.0. Thus the maximum activities for each radionuclide be used in the MK 1.0 have been calculated numerically from the measurement data. The results of these calculations are shown in the following diagrams:

Drawing Number of Isodose Curve	Isotope	Maximum Activity	Shutter Position
Kr85-18,5-10mm-simuliert; Bl.1	Kr-85	500 millicuries (18.5GBq)	unshielded
Kr85-18,5-10mm-simuliert; Bl.2	Kr-85	500 millicuries (18.5GBq)	shielded
Sr90-1,85-35mm-simuliert; Bl.1	Sr-90	50 millicuries (1.85GBq)	unshielded
Sr90-1,85-35mm-simuliert; Bl.2	Sr-90	50 millicuries (1.85GBq)	shielded
Pm147-1,85-10mm-simuliert; Bl.1	Pm-147	50 millicuries (1.85GBq)	unshielded
Pm147-1,85-10mm-simuliert; Bl.2	Pm-147	50 millicuries (1.85GBq)	shielded

Each diagram shows the isodose curves for 2.5 µSv/hr which is equivalent to 0.25 mrem/hr and for 7.5 µSv/hr which is equivalent to 0.75 mrem/hr. The two isodose curves for Pm-147 in the unshielded position (Pm147-1,85-10mm-simuliert; Bl.1) are close together in the measurement gap. The two isodose curves for Pm-147 in the shielded position (Pm147-1,85-10mm-simuliert; Bl.2) are not existing outside the source housing, due to the short range behavior of this radionuclide and the efficient shielding.



5. Labels:

5.1 Address Label

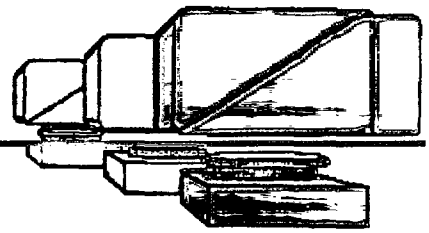
The new design of the label 15 0516 02 contains the information of the betacontrol address in the U.S.

5.2 Information Label

With the label service instructions (see drawing 700-103-737/4) the device MK 1.0 meets the requirements of 10 CFR 32.52 (a)(3)(iii)

betacontrol of America

PO Box 18 • 425 Route 202 • Towaco, NJ 07082 • Tel.: 973-263-0477 • Fax. 973-263-0477



Section 2

Drawing List

No	Drawing Number	Denotation	Description
1	700-010-590/2	O-Frame	The O-Frame remains the same for the new sensor (drawing S01-103-001-3) and old sensor (drawing 700-103-559/3 d) MK 1.0
2	S01-103-001-3	Sensor MK 1.0 new Version	The Sensor is a combination of source housing (lower part, drawing S04-041-030-3) and detector (upper part).
3	700-103-559/3 d	Sensor MK 1.0 old Version	The Sensor is a combination of source housing (lower part, drawing 700-3241/3) and detector (upper part).
4	S04-41021	Source housing MK 1.0 new Version detail drawing	The drawing gives detail information about safety related features.
5	Service instructions	Source housing MK 1.0 new Version service instructions	Three pictures are showing the process of changing the shielding foil at the source housing new version.
6	700-3241/3	Source housing MK 1.0 old Version	This type of source housing is fitted for one source.
7	15 0516 02	Label with address information for MK 1.0 new Version	The Label is mounted to the source housing above the window.
8	Radioactive label	Label with source information for MK 1.0 new Version	The Label is mounted to the source housing on the left and the right site.
9	700-103-737/4	Label with maintenance instructions	The Label is mounted to the source housing.
10	Address and radioactive label	Labels for source housing MK 1.0 old Version	Both labels are mounted to the source housing on the left and the right side.
11	S04-52001-3	Shielding Kr-85 for MK 1.0 new Version	This shielding is located inside the source housing (drawing S04-041-030-3).
12	S04-52005-3	Shielding Sr-90 for MK 1.0 new Version	This shielding is located inside the source housing (drawing S04-041-030-3).
13	S04-52007-3	Shielding Am 241 / Pm 147 for MK 1.0 new Version	This shielding is located inside the source housing (drawing S04-041-030-3).
14	Kr85-18,5-10mm-simuliert; Bl.1	Isodose curves for Kr-85, 500 millicuries (18.5GBq) for MK 1.0 new Version source unshielded	These curves for an activity of 500 millicuries (18.5GBq) were calculated from the measurement data of the new Version MK 1.0 with an activity of 9.9 GBq.
15	Kr85-18,5-10mm-simuliert; Bl.2	Isodose curves for Kr-85, 500 millicuries (18.5GBq) for MK 1.0 new Version source shielded	These curves for an activity of 500 millicuries (18.5GBq) were calculated from the measurement data of the new Version MK 1.0 with an activity of 9.9 GBq.
16	Sr90-1,85-35mm-simuliert; Bl.1	Isodose curves for Sr-90, 50 millicuries (1.85GBq) for MK 1.0 new Version source unshielded	These curves for an activity of 50 millicuries (1.85GBq) were calculated from the measurement data of the new Version MK 1.0 with an activity of 0.37 GBq.
17	Sr90-1,85-35mm-simuliert; Bl.2	Isodose curves for Sr-90, 50 millicuries (1.85GBq) for MK 1.0 new Version source shielded	These curves for an activity of 50 millicuries (1.85GBq) were calculated from the measurement data of the new Version MK 1.0 with an activity of 0.37 GBq.
18	Pm147-1,85-10mm-simuliert; Bl.1	Isodose curves for Pm-147, 50 millicuries (1.85GBq) for MK 1.0 new Version source unshielded	These curves for an activity of 50 millicuries (1.85GBq) were calculated from the measurement data of the new Version MK 1.0 with an activity of 18.5 GBq.
19	Pm147-1,85-10mm-simuliert; Bl.2	Isodose curves for Pm-147, 50 millicuries (1.85GBq) for MK 1.0 new Version source shielded	These curves for an activity of 50 millicuries (1.85GBq) were calculated from the measurement data of the new Version MK 1.0 with an activity of 18.5 GBq.

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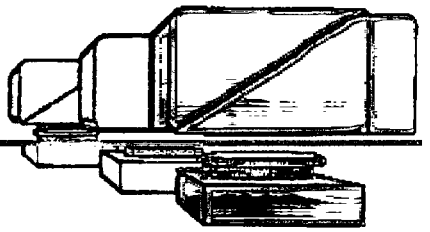
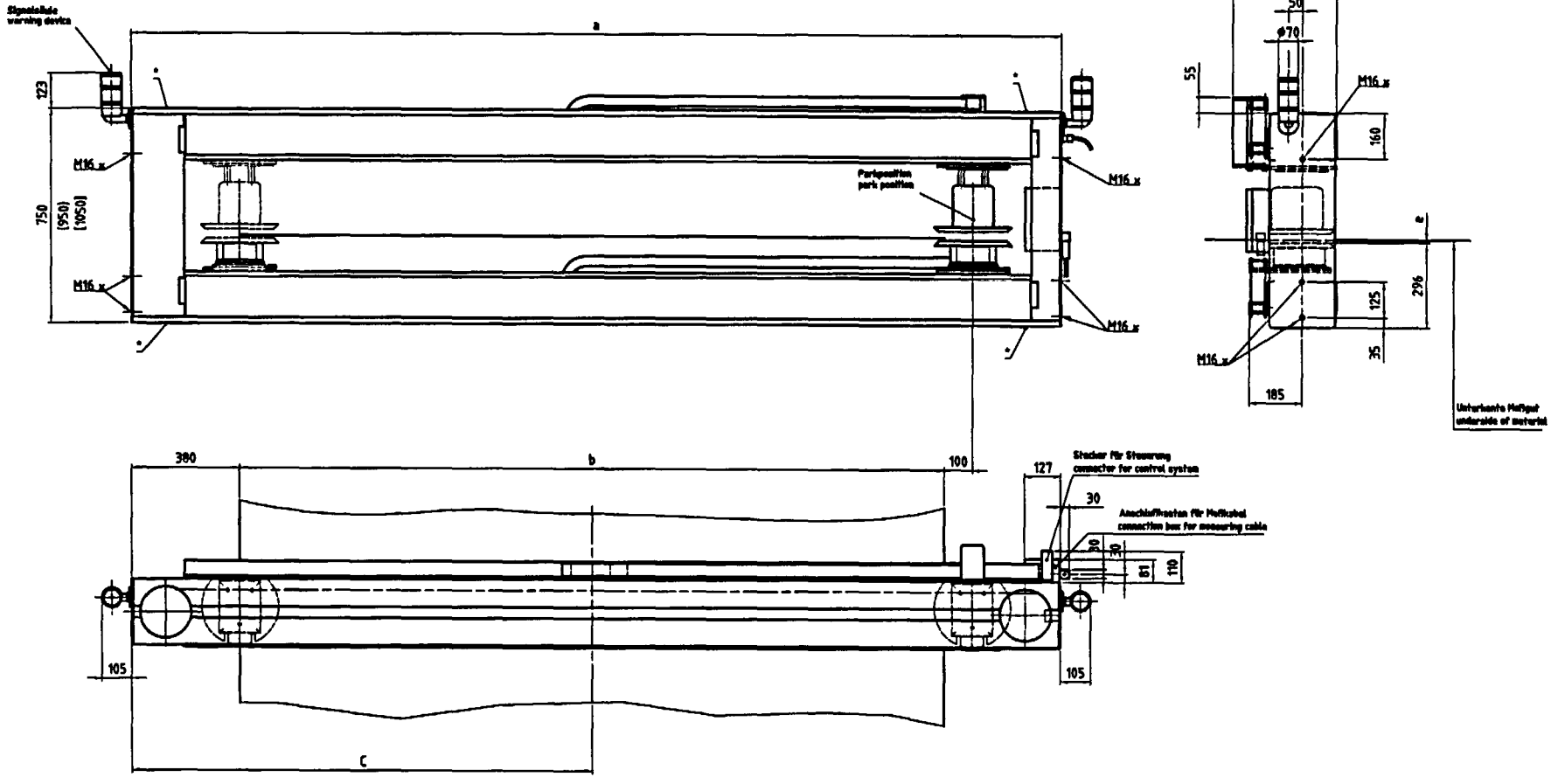


Section 3

Appendix List

No	Page Number	Denotation	Description
1	-	ISO 9001:2000 Certificate	ISO 9001:2000 Certificate of Betacontrol GmbH
2	B32	Sr-90, SIF.D1	Description of the AEA source model Sr-90, SIF.D1
3	B28	Kr-85, KAC.D1	Description of the AEA source model Kr-85, KAC.D1
4	B27	Kr-85, KAC.D3	Description of the AEA source model Kr-85, KAC.D3
5	B2	Am-241, AMC.17	Description of the AEA source model Am-241, AMC.17
6	B31	Pr-147, PHC.C1	Description of the AEA source model Pr-147, PHC.C1
7	C1	Quality Control 1.	Description of the AEA quality control measures
8	C2	Quality Control 2.	Description of the AEA quality control measures
9	E1	Source Safety 1.1	Description of the AEA source safety
10	E2	Source Safety 1.2	Description of the AEA source safety
11	E3	Source Safety 2.	Description of the AEA source safety
12	E4	Source Safety 2.	Description of the AEA source safety



Traversengröße travelling table		1	2	3	4	5	6
Gesamtbreite total width	a	1740	2250	2760	3270	3780	4290
× max. Meßgutbreite max. material width	b	950	1460	1970	2480	2990	3500
Mitte Meßgut middle material	c	855	1110	1365	1620	1875	2130
wird von betacontrol festgelegt determined by betacontrol	e						

× Befestigungs - Bohrungen
mounting holes
trous de montage

* Wartungsöffnung freihalten
Opening for service to be kept free

Allgemeintoleranzen DIN ISO 2768-f

Maßstab 1:10

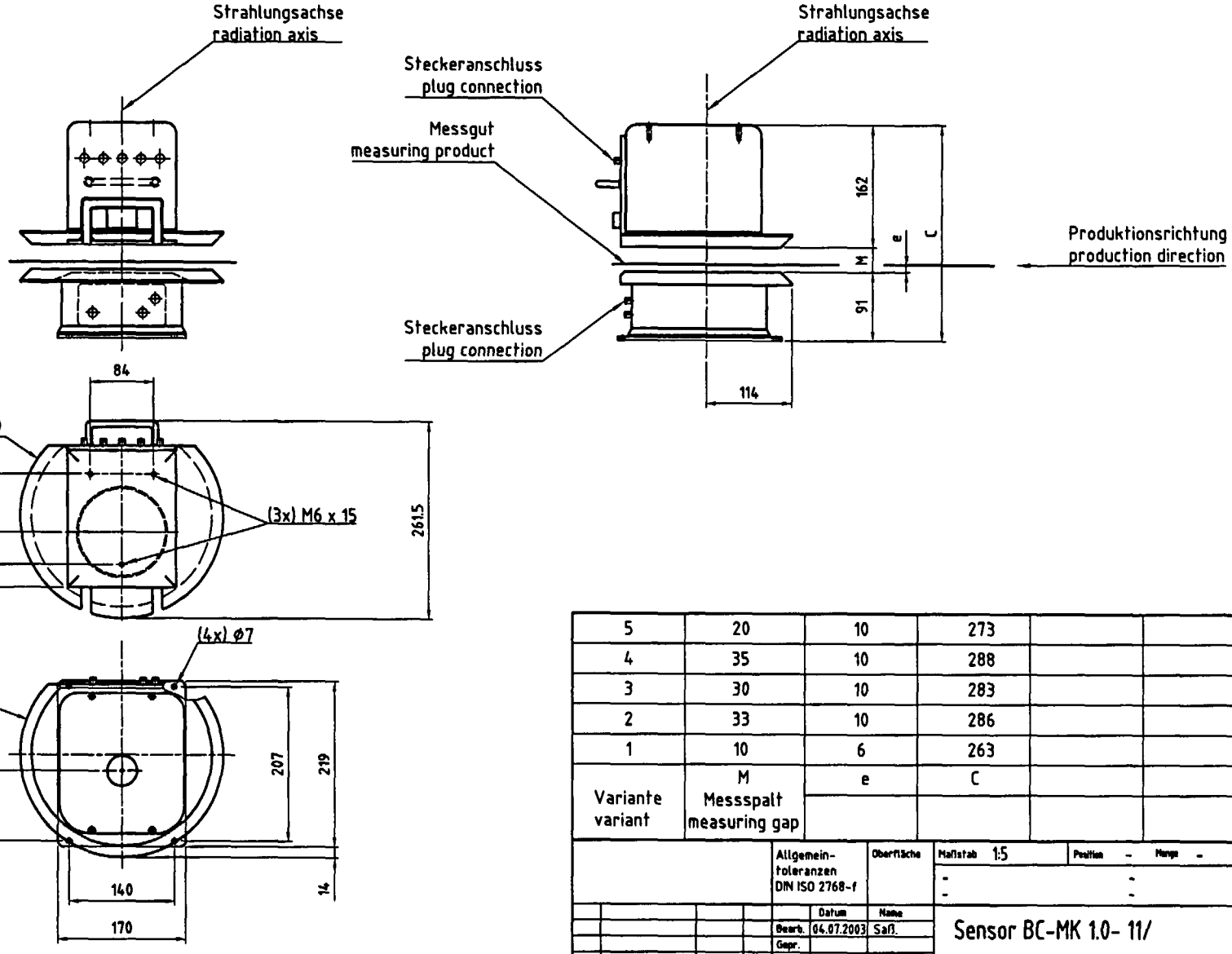
Bearb. 03.04.2003 Sef

Gepr. 03.04.2003 Pioch

betacontrol

Maßbild für Traverse
dimension drawing c-frame

700-010-590/2



5	20	10	273		
4	35	10	288		
3	30	10	283		
2	33	10	286		
1	10	6	263		
Variante variant	M Messspalt measuring gap	e	C		

Nr.	Datum	Änderung	Bearbeiter
b	26.05.2004	Bezeichnung in BC-MK... geä.	Safi
a	19.04.2004	Maß 204 in 207 geä.	Safi

Zust.	Änderungen	Datum	Name

Allgemeintoleranzen DIN ISO 2768-f

Oberfläche

Maßstab 1:5 | Position - | Menge -

	Datum	Name
Bearb.	04.07.2003	Safi.
Gepr.		
Norm		

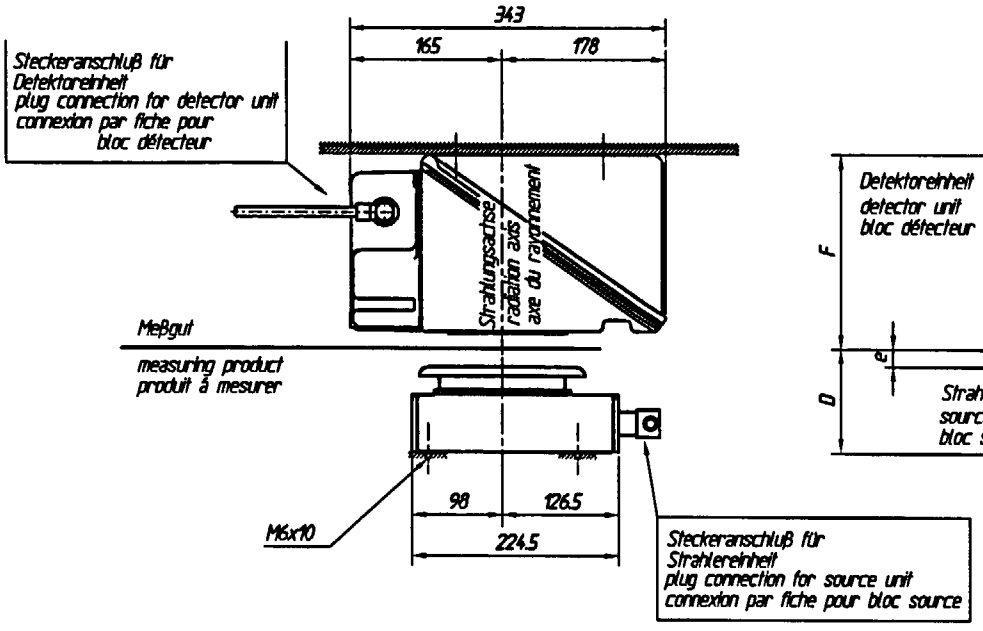
Sensor BC-MK 1.0- 11/

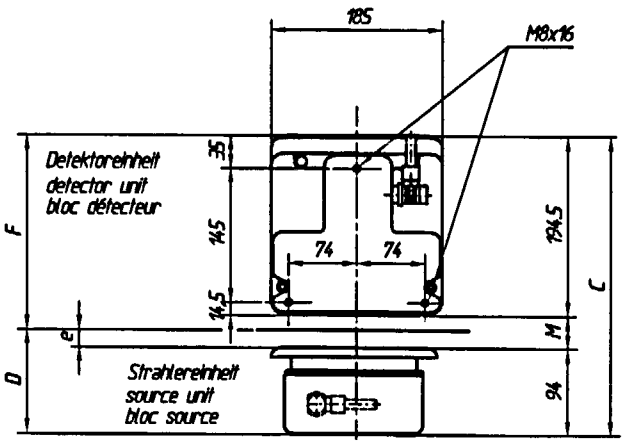
sensor BC-MK-1.0-11/

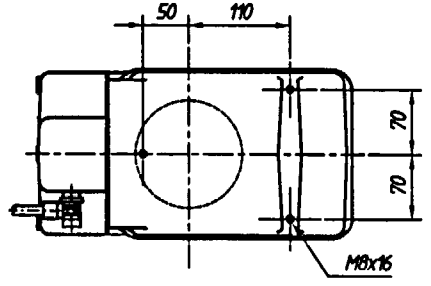
betacontrol

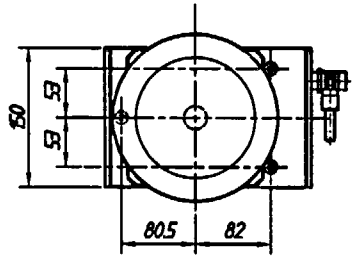
S01-103-001-3

Blatt -









XIII		9,5	298	4	98	200
XII		40	328,5	20	114	234,5
XI		15	303,5	6	100	209,5
X		400	688,5	10	104	584,5
IX		450	738,5	10	104	634,5
VIII		103	391,5	10	104	287,5
VII		50	338,5	10	104	234,5
VI		9,5	298	6	100	198
V		20	308,5	10	104	214,5
IV		335	623,5	10	104	519,5
III		235	523,5	10	104	419,5
II		72,5	361	37	131	230
I		33	321,5	10	104	217,5
Variante variant variante		M Meßspalt measuring gap fente de mesure	C	e	D	F
			Maße / dimensions / dimensions			

Nr.	Änderung	Datum	Name
"d"	Variante XIII nachgetragen	29.04.03	Saß.
"c"	Variante XII nachgetragen u. auf kleiner Stecker geändert	17.01.2001	Stolzel
"b"	Variante XI nachgetragen.	27.199	Saß.

	Datum	Name
Gezeichnet	24.07.1995	Barthel
Geprüft	27.01.99	Saß.

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Maßstab 1:5

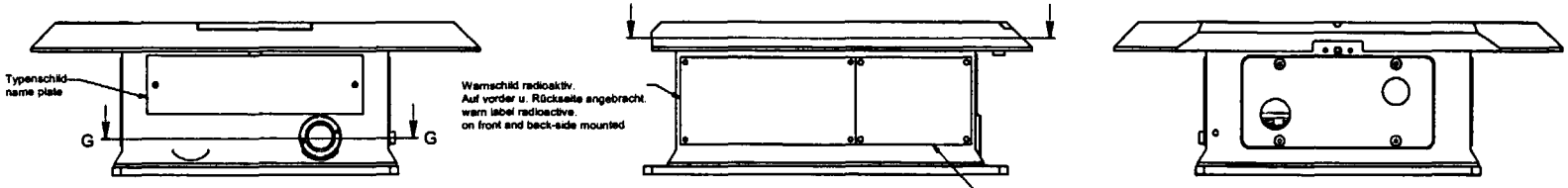
Meßfühler BC-MK 1.0

measuring sensor BC-MK 1.0

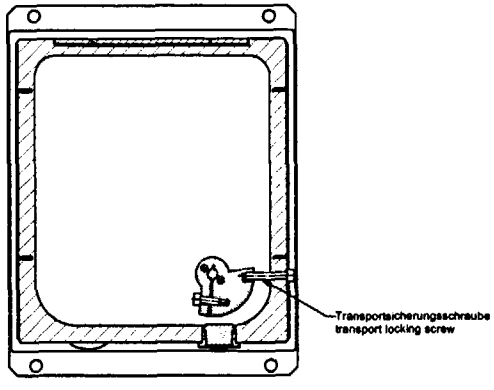
jauge BC-MK 1.0

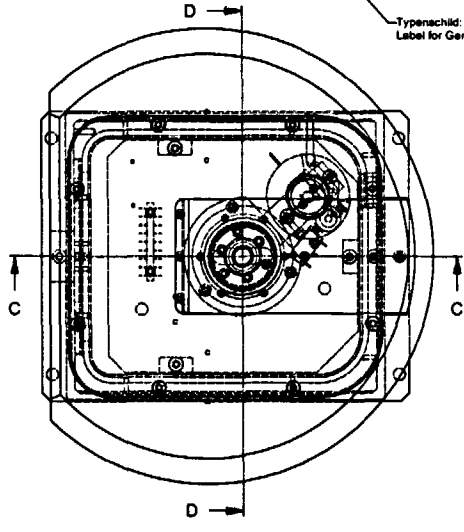
700-103-559/3 d

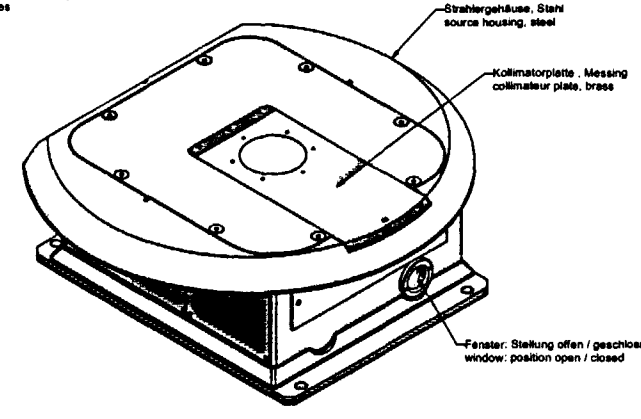
Ersatz für : 700-103-160/3



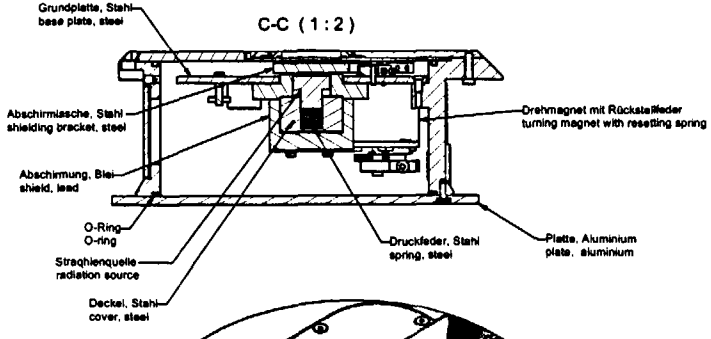
G-G (1 : 2)



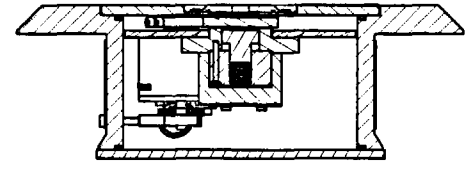




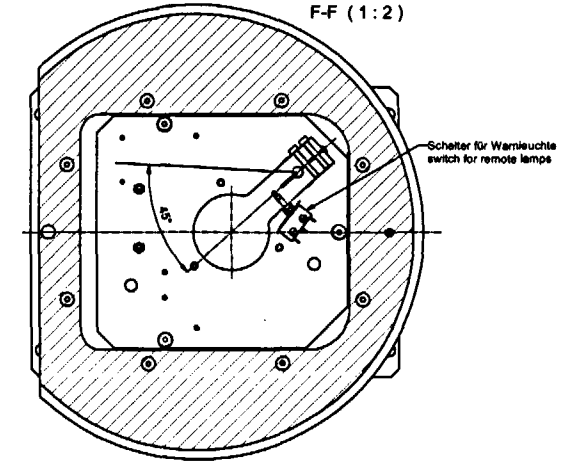
C-C (1 : 2)

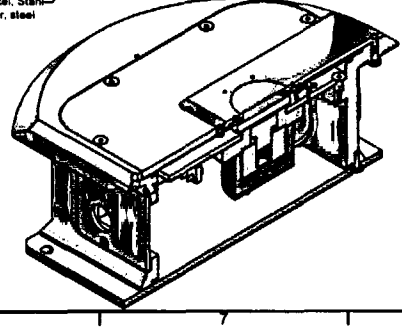


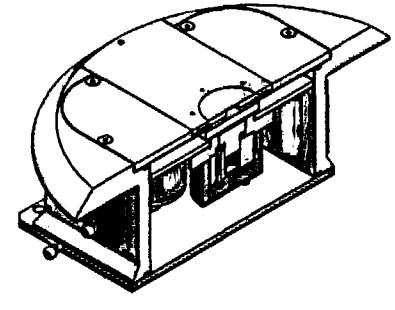
D-D (1 : 2)



F-F (1 : 2)







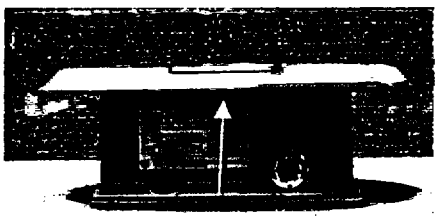
		Allgemeintoleranzen DIN ISO 2768-f		
		Datum	Name	Strahlereinheit BC-MK1.0-
		Gezeichnet 20.08.2004	Saß	Source housing BC-MK1.0-
		Geprüft		
		Norm		S04-41021
Benut	Änderungen	Datum	Name	1 / A2

Sensor: Replacing shielding foils

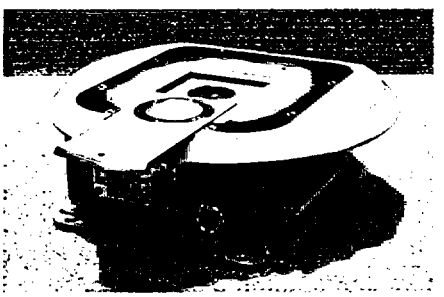
Replacing the shielding foil (emitter unit)

1.) Turn off the ***main power switch.***

2.) Remove the lock screw for the foil frame (Allen wrench, 3 mm)

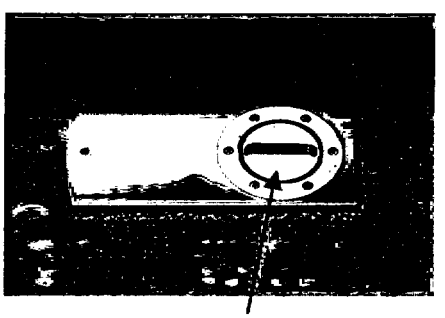


3.) Remove the foil frame.



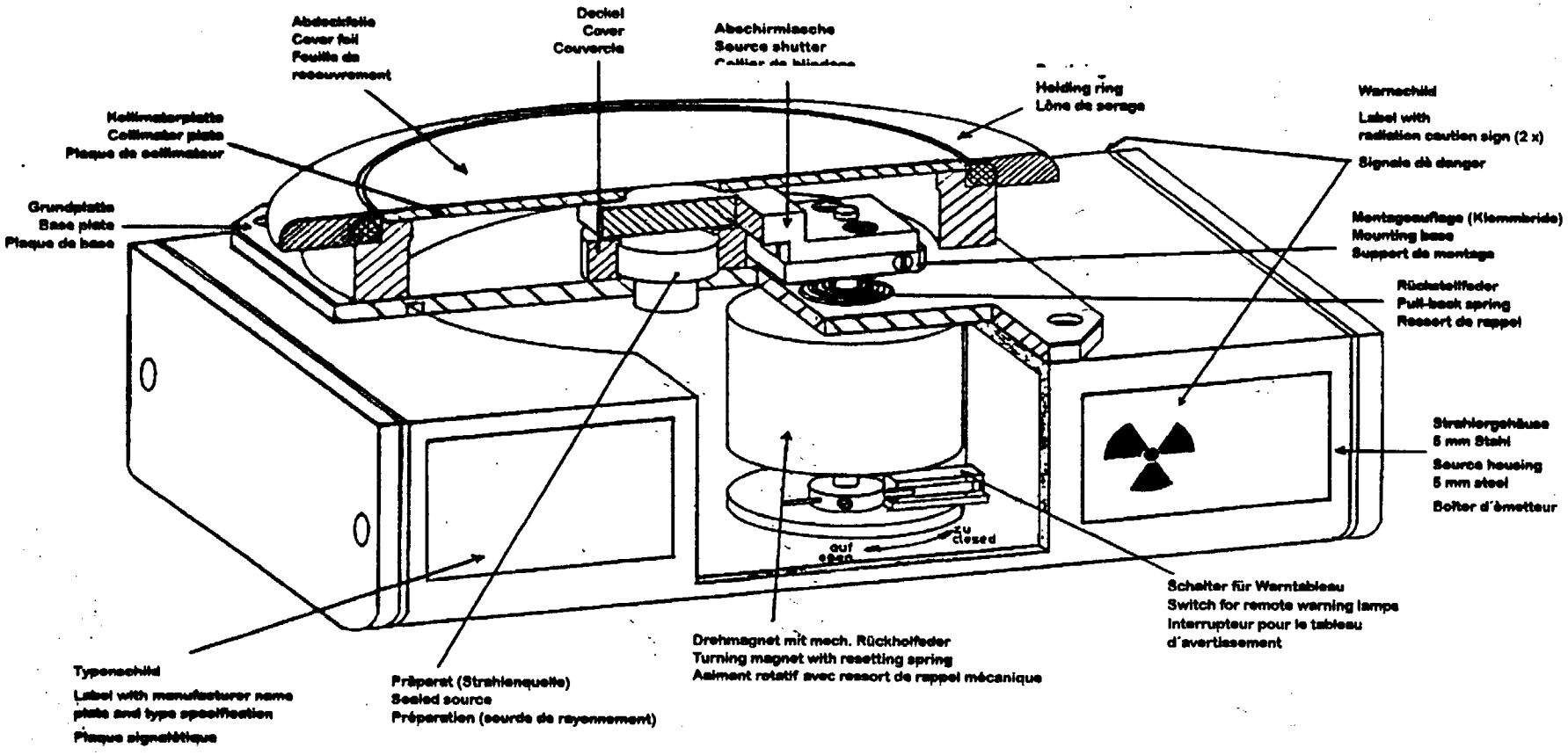
4.) Remove the collimator pane in the foil frame. Remove the defective shielding foil. Insert new foil and screw the collimator pane back in place. Carefully trim away excess foil.

.



Gasket

5.) Replace the foil frame.
Ensure that the gasket is correctly positioned in the groove!

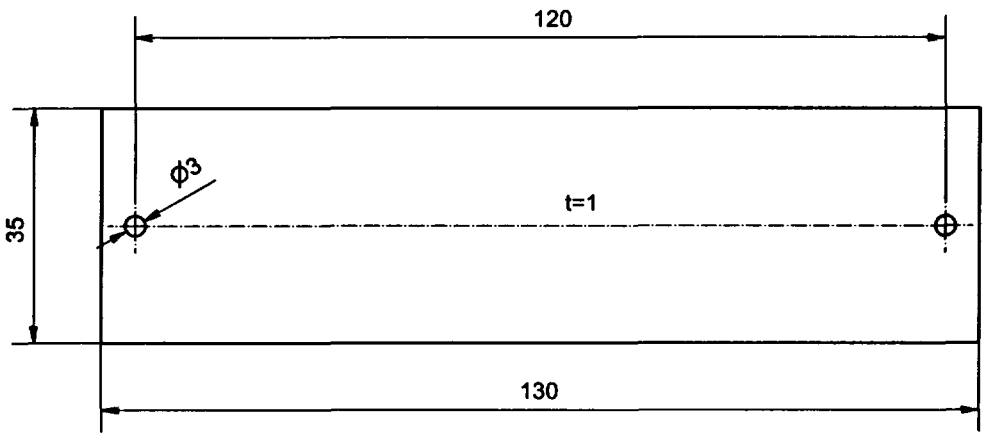


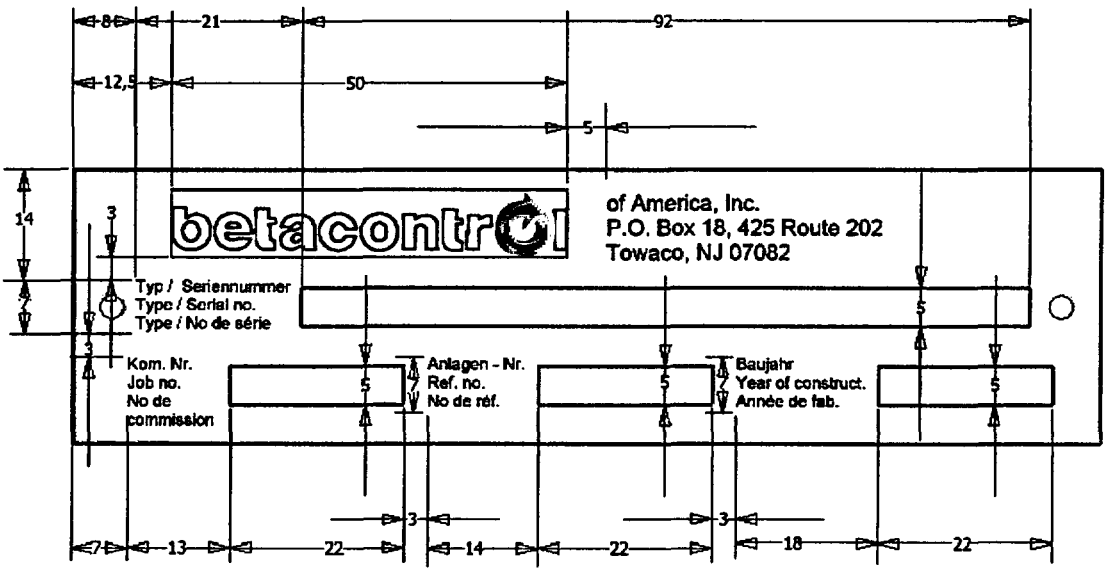
	Datum:	Name:		
Gezeichnet:	2.6.00			betacontrol gmbH D-57258 Freudenberg
Geprüft:	30.5.00			

Strahlereinheit

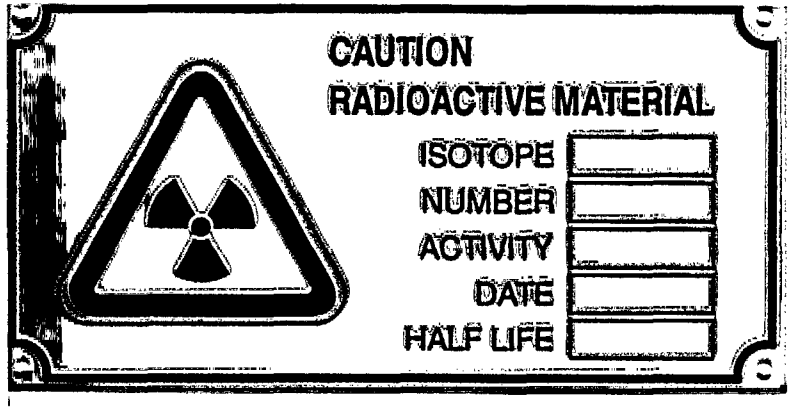
Source housing
bloc émetteur

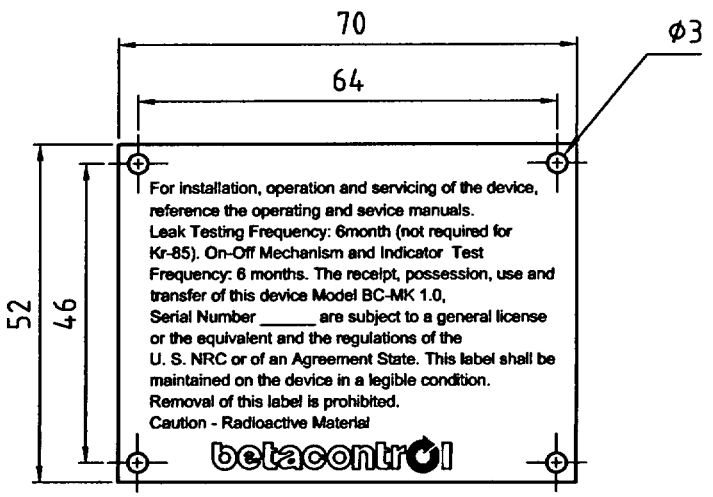
700 - 3241 / 3





				Allgemein-toleranzen DIN ISO 2768-f			AlMg3
					Datum	Name	Typenschild label
				Gezeichnet	23.08.2004	Saß	
				Kontrolliert			
				Norm			
							15 0516 02
							1 / A4
Status	Änderungen	Datum	Name				


CAUTION
RADIOACTIVE MATERIAL
ISOTOPE
NUMBER
ACTIVITY
DATE
HALF LIFE

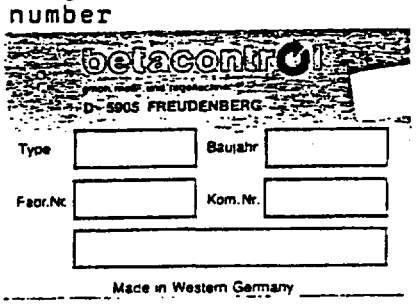


				Allgemeintoleranzen DIN ISO 2768-f		Oberfläche	Maßstab 1:1	Position –	Menge –
							Bl. 1 x 52 x 69 –	– AlMg3	
					Datum	Name	Schild USA		
				Bearb.	19.08.04	Saß.			
				Gepr.					
				Norm					
				betacontrol			700-103-737/4		Blatt – Bl
Zust.	Änderungen	Datum	Name	Dateiname –					

Labelling:

Two labels are visibly fitted.

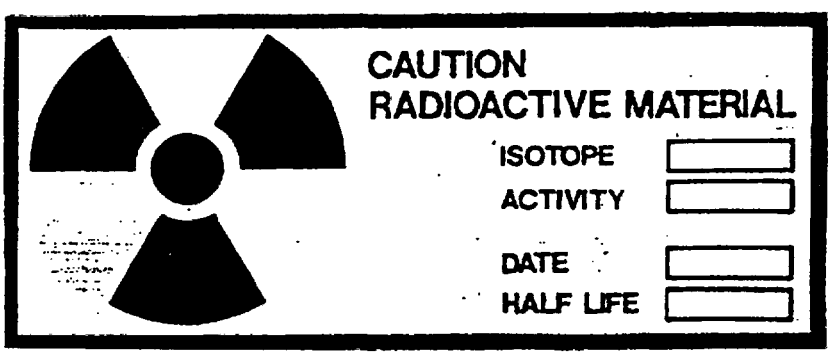
The first label is made of aluminium and states:
- manufacturer's name
- type of source housing and year of construction
- apparatus and job number

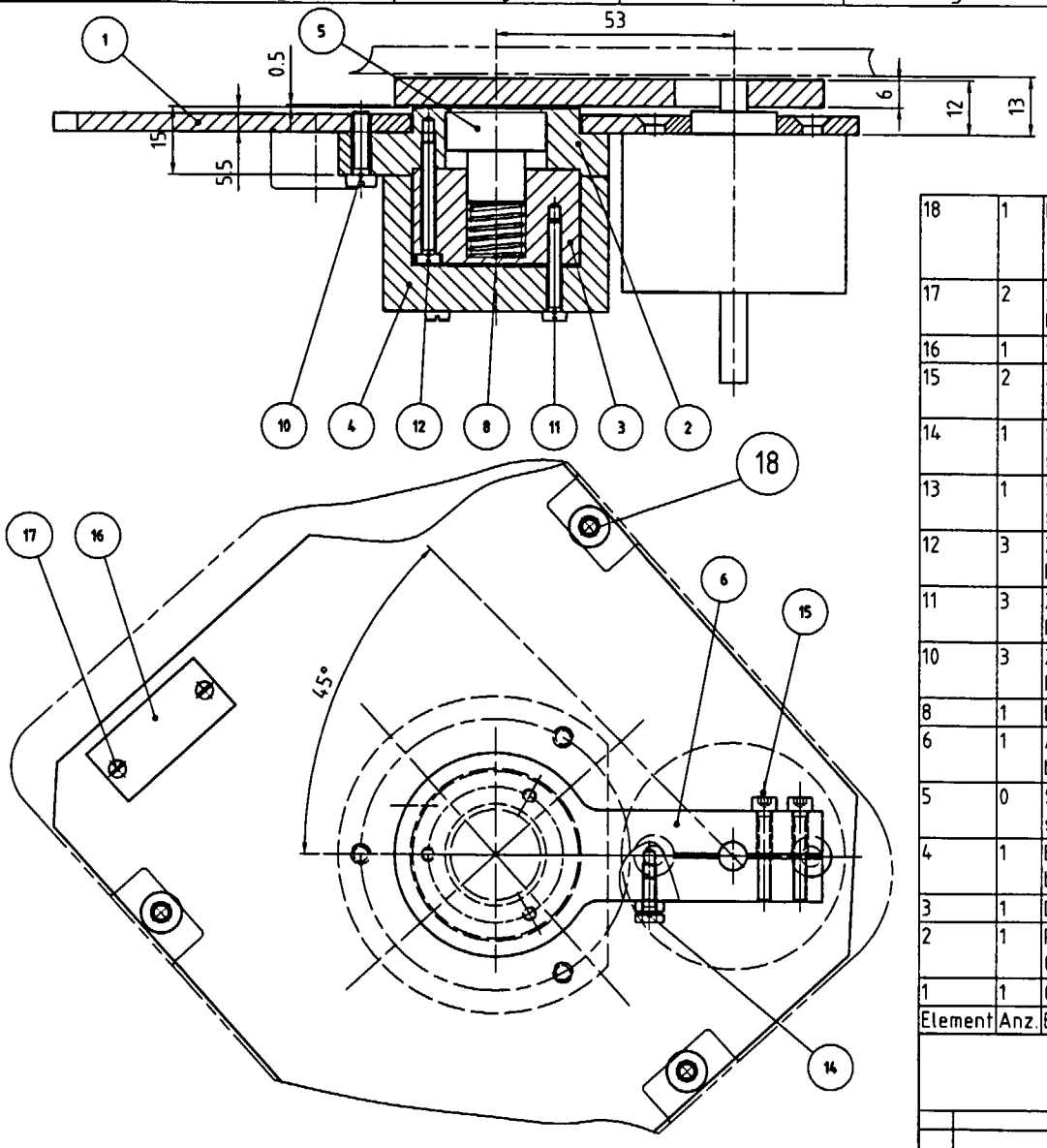


← ORIGINAL AFFIXED TO DWG# 700-3241-3

The second label is fitted on the 2 opposite sides of the source housing each. It is made of aluminium and states:
- radiation caution sign
- isotope name and atomic number
- activity
- date of delivery
- half life

ORIGINAL → AFFIXED TO DWG# 700-3241-3





18	1	Innensechskantschraube mit Senkkopf _ Allen countersunk screw	ISO 10642 - M4 x 12	A2
17	2	Zylinderschraube mit Schlitz _ Fillister head screw	DIN 912- M2 x 4	A2
16	1	Schild _ Name plate	700-052-025/4	A2
15	2	Zylinderschraube _ Allen head screw	DIN 912 - M3 x 20	A2
14	1	Sechskantschraube _ Hex head screw	DIN 933 - M3 x 8	A2
13	1	Sechskantmutter _ Hex head screw	DIN 934 - M3	A2
12	3	Zylinderschraube mit Schlitz _ Fillister head screw	ISO 1207 - M3 x 25	A2
11	3	Zylinderschraube mit Schlitz _ Fillister head screw	ISO 1207 - M3 x 20	A2
10	3	Zylinderschraube mit Schlitz _ Fillister head screw	ISO 1207 - M4 x 14	A2
8	1	Druckfeder _ Spring	VD-179K	1.4310
6	1	Abschirmlasche _ Shielding bracket	S04-052-014-4	S235JR
5	0	Strahlenquelle _ Radiation sousce	X.1114	
4	1	Bleiabschirmung _ Shielding bracket	S04-052-009-4	Pb
3	1	Deckel _ Cover	S04-052-008-4	S235JR
2	1	Präparathalter oben _ Compound holder	S04-052-005-4	S235JR
1	1	Grundplatte _ Base plate	S04-041-024-3	S235JR
Element	Anz.	Beschreibung	Standard	Material

Allgemeintoleranzen DIN ISO 2768-f

Oberfläche

Maßstab 1:1 | Position - | Menge -

	Datum	Name
Bearb.	11.02.2003	Saß.
Gepr.	11.02.03	Pioch
Norm		

Strahlerabschirmung Kr 85

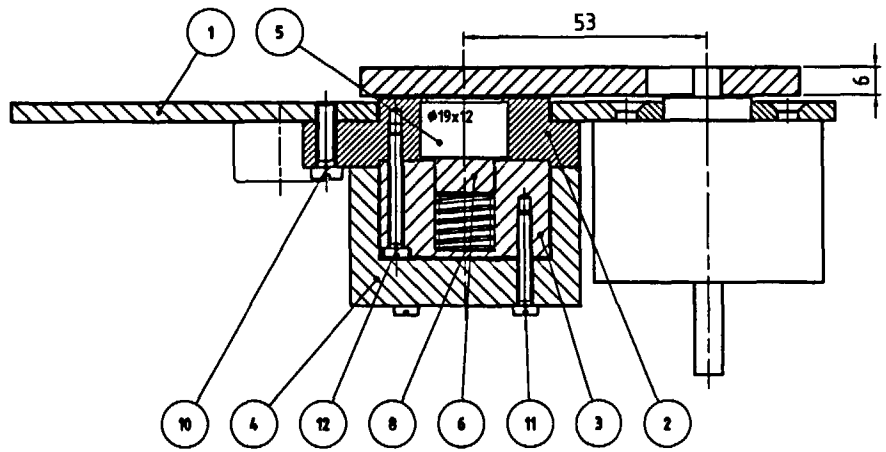
shielding Kr 85

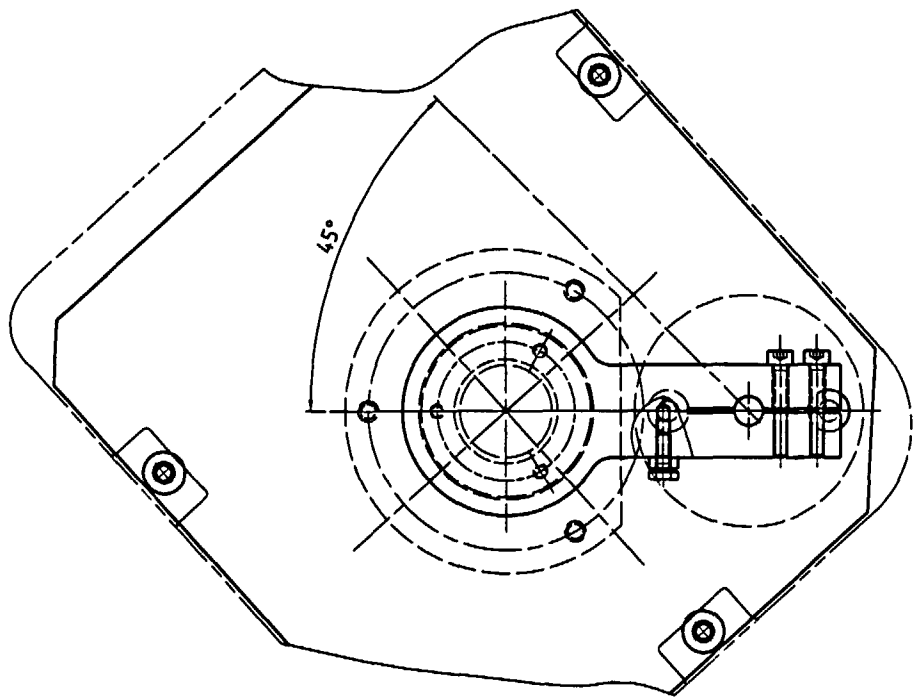
betacontrol

S04-52001-3

Blatt -

Zust. | Änderungen | Datum | Name | Dateiname





Element	Anz.	Beschreibung	Material	Standard
12	3	Zylinderschraube mit Schlitz	Fillister head screw	ISO 1207 - M3 x 25
11	3	Zylinderschraube mit Schlitz	Fillister head screw	ISO 1207 - M3 x 20
10	3	Zylinderschraube mit Schlitz	Fillister head screw	ISO 1207 - M4 x 14
8	1	Druckfeder	Spring	VD-179K
6	1	Druckstange	Spacer	S04-052-010/4
5	0	Strahlenquelle	Radiation source	X.117
4	1	Bleiabschirmung	Shield	S04-052-009-4
3	1	Deckel	Cover	S04-052-008-4
2	1	Präparathalter oben	Compound holder	S04-052-006-4
1	1	Grundplatte	Base plate	S04-041-024-3

Allgemeintoleranzen DIN ISO 2768-f

Oberfläche

Maßstab 1:1

Position - Menge -

	Datum	Name
Bearb.	11.02.2003	Saß.
Gepr.	18.02.03	Weber
Norm		

Strahlerabschirmung Sr 90

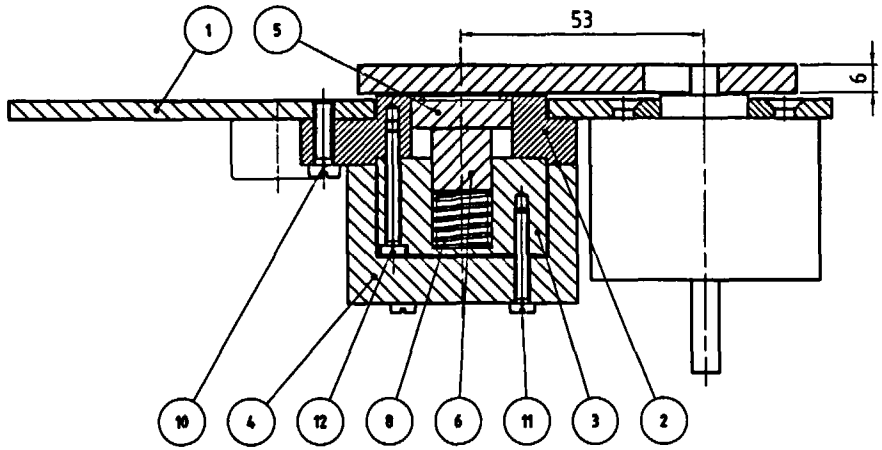
shielding Sr 90

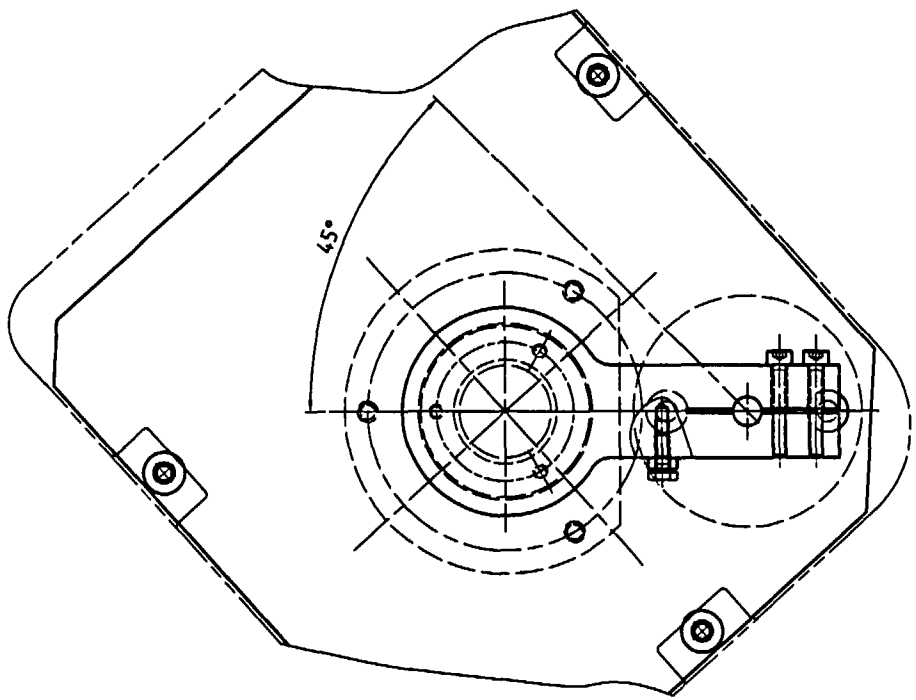
betacontrol

S04-52005-3

Blatt -

Zust. Änderungen Datum Name Dateiname





Element	Anz.	Beschreibung	Material	Standard
12	3	Zylinderschraube mit Schlitz	Fillister head screw	ISO 1207 - M3 x 25
11	3	Zylinderschraube mit Schlitz	Fillister head screw	ISO 1207 - M3 x 20
10	3	Zylinderschraube mit Schlitz	Fillister head screw	ISO 1207 - M4 x 14
8	1	Druckfeder	Spring	VD-179K
6	1	Druckstange	Spacer	S04-052-010/4
5	0	Strahlenquelle	Radiation source	
4	1	Bleiabschirmung	Shield	S04-052-009-4
3	1	Deckel	Cover	S04-052-008-4
2	1	Präparathalter oben	Compound holder	S04-052-006-4
1	1	Grundplatte	Base plate	S04-041-024-3

Allgemeintoleranzen DIN ISO 2768-f

Oberfläche

Maßstab 1:1

Position – Menge –

	Datum	Name
Bearb.	11.02.2003	Saß.
Gepr.	18.02.03	Weber
Norm		

Strahlerabschirmung Am 241 / Pm 147

shielding Am 241 / Pm 147

betacontrol

S04-52007-3

Blatt –

Zust. Änderungen Datum Name Datei:

ZERTIFIKAT

Hiermit wird bescheinigt, dass das Qualitätsmanagementsystem von:

betacontrol gmbh mess- und regeltechnik
Am Weidekamp 10, 57258 Freudenberg
Deutschland

durch Lloyd's Register Quality Assurance geprüft und bewertet wurde und den folgenden Normen zum Qualitätsmanagement entspricht:

ISO 9001:2000

Das Qualitätsmanagementsystem ist anwendbar für:

Entwicklung und Herstellung von Mess- und Regelanlagen.

Zertifikat
Registrier-Nr: KLN 0201749

Erstmalige Zulassung: *5. Juni 1996*

Bestehendes Zertifikat: *23. Juli 2003*

Dieses Zertifikat ist gültig bis: *31. Mai 2005*

Ausgestellt von: LRQA GmbH

UKAS QUALITY MANAGEMENT
001

Dieses Dokument unterliegt der umseitigen Bestimmung.

Diese Zertifizierung wurde gemäß den LRQA-Verfahren zur Auditierung und Zertifizierung durchgeführt. Diese Verfahren werden von LRQA überwacht.
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Macro Revision 10.1

Strontium-90 (+Yttrium-90)

Beta Sources

Disc Sources (ceramic)

A Strontium-90 compound incorporated on a ceramic insert, doubly encapsulated in stainless steel, inner capsule with 25µm stainless steel window, outer capsule with 50µm stainless steel window.

Nominal activity* MBq	mCi	Capsule	Product code
74	2	X.117	SIF1171
370	10	X.117	SIF1174
740	20	X.117	SIF1175
1850	50	X.117	SIF1176
3700	100	X.117	SIF1177

*Tolerance ±25%

A Strontium-90 compound incorporated on a ceramic insert. *Single encapsulated in stainless steel with 0.1mm stainless steel* window.

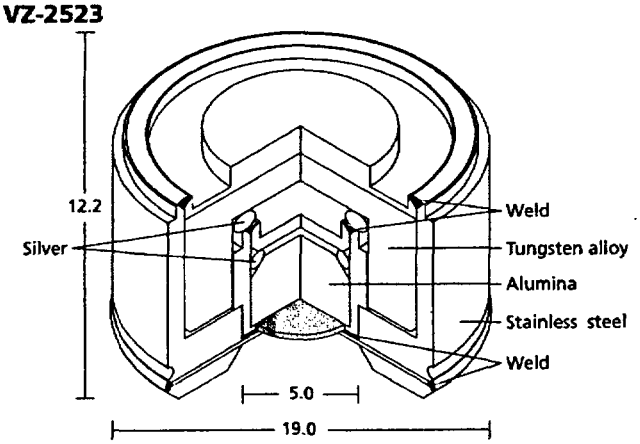
Nominal activity* MBq	mCi	Capsule	Product code
74	2	VZ-2453/1	SIFB12009
185	5	VZ-2453/1	SIFB11884
555	15	VZ-2453/1	SIFB11369
1850	50	VZ-2453/1	SIFB11885
3700	100	VZ-2453/1	SIFB12010

*Tolerance ±15%

Recommended working life: 10 years

Quality Control
Wipe test I
Immersion test II

X.117*
VZ-2523

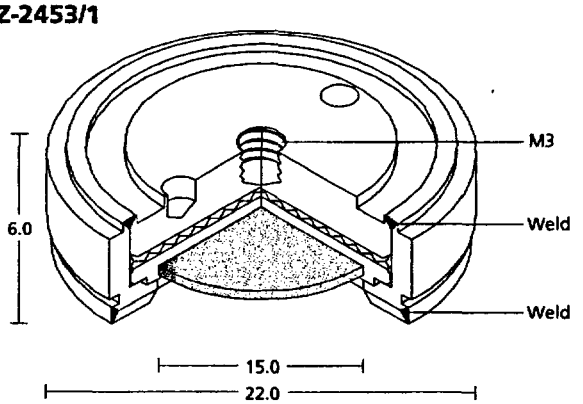


Safety performance testing

ANSI/ISO classification	IAEA special form	US-Model number
C64343	GB/171/S-96	SIF.D1

*X.117 *manufactured acc. to drg.VZ-2523*

VZ-2453/1



Safety performance testing

ANSI/ISO classification
C43324

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Hong Kong: AEA Technology QSA, Room 3503, 35/F, China Resources Building,
26 Harbour Road, Wanchai, Phone No: +852 2596 7711
Germany: AEA Technology QSA GmbH, Gieselweg 1, 38110 Braunschweig, Phone No: +49 (0)5307 9320
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Krypton-85

Beta Sources

Low bremsstrahlung, high output sources

Krypton-85 gas is encapsulated in welded titanium capsules with a 25µm thick titanium window. Each capsule has a copper fill tube at the back, which is sealed by cold welding and then soldering. The inclusion of a welded back cap provides a secondary seal to protect the cold welded copper tube and provide improved mechanical strength.

A protective window shield is included with each source to protect the window during transportation and handling. It also absorbs the beta dose from the source making it easy for the user to handle and load into gauging devices.

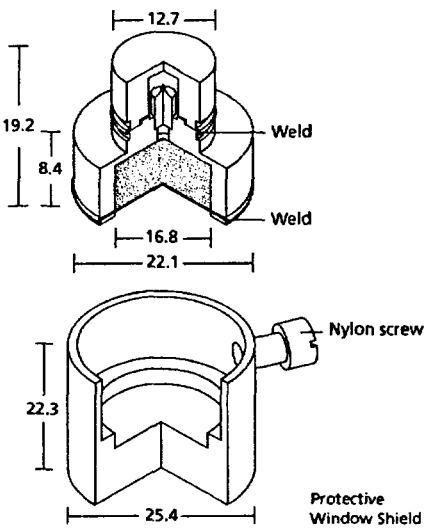
Nominal activity* GBq	mCi	Capsule	Product code
3.7	100	X.1114	KAC11401
7.4	200	X.1114	KAC11402
11.1	300	X.1114	KAC11403
18.5	500	X.1114	KAC11405
37.0	1000	X.1114	KAC11410
1.85	50	X.1266/3	KACK5565
7.4	200	X.1266/3	KACK7807
11.1	300	X.1266/3	KACK5674
18.5	500	X.1266/3	KACK7654
37.0	1000	X.1266/3	KACK8148

*Tolerance ±10%

Recommended working life: 10 years

Quality Control
Emanation test V + VI

X.1114*
VZ-2820

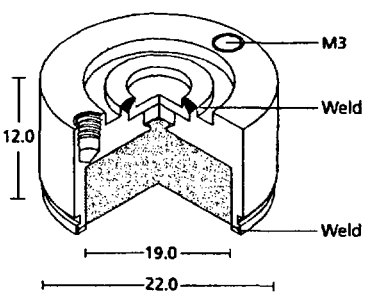


Safety performance testing

Capsule	ANSI/ISO classification	US-Model number
VZ-2820	C33332	KAC.D1
VZ-2866	C42341	

*X.1114 manufactured acc. to drg.VZ-2820

X.1266*
VZ-2866



*X.1266 manufactured acc. to drg.VZ-2866

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Germany: AEA Technology QSA GmbH, Gieselweg 1, 38110 Braunschweig, Phone No: +49 (0)5307 9320
France: AEA Technology QSA, 12 Avenue des Tropiques, Hightec Sud - Bâtiment B,
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Krypton-85

Beta Sources

Low bremsstrahlung, high output sources

Krypton-85 gas is encapsulated in welded titanium capsules with a 25µm thick titanium window. Each capsule has a copper fill tube at the back, which is sealed by cold welding and then soldering. The inclusion of a welded back cap provides a secondary seal to protect the cold welded copper tube and provide improved mechanical strength.

A protective window shield is included with each source to protect the window during transportation and handling. It also absorbs the beta dose from the source making it easy for the user to handle and load into gauging devices.

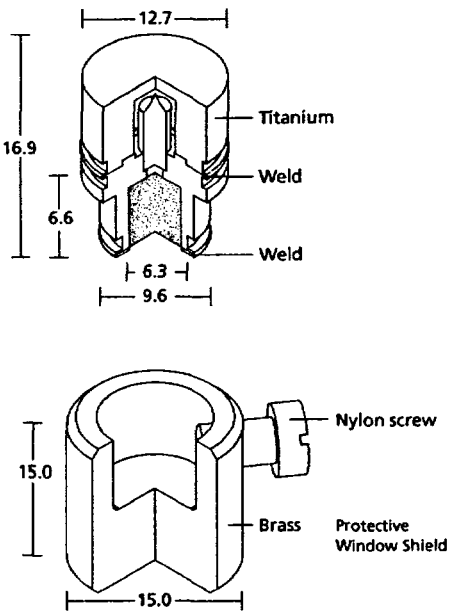
Nominal activity* GBq	mCi	Capsule	Product code
3.7	100	X.1088	KAC10881
7.4	200	X.1088	KAC10882
11.1	300	X.1088	KAC10883
14.8	400	X.1088	KAC10884

*Tolerance ±10%

Recommended working life: 10 years

Quality Control
Emanation test V + VI

X.1088*
VZ-2832



Safety performance testing

ANSI/ISO classification	US-Model number
C43332	KAC.D3

*X.1088 manufactured acc. to drg.VZ-2832

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Germany: AEA Technology QSA GmbH, Gieselweg 1, 38110 Braunschweig, Phone No: +49 (0)5307 9320
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Americium-241

γ and Primary X-ray Sources

Disc Sources, Stainless Steel Window

Americium-241 incorporated in a ceramic enamel, sealed in a welded stainless steel capsule.

Nominal activity*		Capsule	Typical photon output in photons/s per steradian	Product code
GBq	mCi		59.5keV	
3.7	100	X.91	53.0×10^6	AMC16
11.1	300	X.92	150.0×10^6	AMC17
18.5	500	X.97	280.0×10^6	AMC18
37	1000	X.93	500.0×10^6	AMC19
111	3000	X.94	1.2×10^9	AMC30
185	5000	X.95	2×10^9	AMC50

*Tolerance ±10%

Recommended working life: 15 years

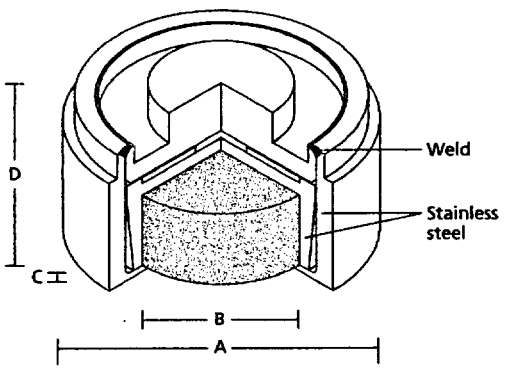
Quality Control
Wipe test I
Immersion test II
Bubble test III

59.5keV γ-ray emission is measured in narrow beam geometry using a thin NaI detector.

Spectral purity is checked using Si (Li), Ge and NaI detectors.

Neutron emission
All Americium-241 sources emit 0.3n/s per MBq (~10^4n/s per Ci) due to (α, n) reactions with the low atomic number elements (for example, Si, Al, O) in the active material.

X.91-95, 97



Capsule dimensions and Safety performance testing

Capsule	Overall diam. 'A'mm	Active diam. 'B'mm	Window thickness 'C'mm	Overall thickness 'D'mm	Safety performance testing ANSI/ISO classification	IAEA special form	US-Model number
X.91	10.8	7.5	0.2–0.25	6.0	C64444	GB/38/S-96	AMC.16
X.92	15.0	12.0	0.2–0.25	6.0	C64444	GB/39/S-96	AMC.17
X.93	30.0	25.0	0.2–0.25	6.0	C64444	D/0089/S-96	AMC.19
X.94	36.0	31.0	0.25–0.3	8.0	E64444	GB/107/S-96	AMC.30
X.95	45.0	40.0	0.25–0.3	8.0	E64444	GB/121/S-96	AMC.50
X.97	22.0	18.0	0.2–0.25	6.0	C64444	GB/41/S-96	AMC.18

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Promethium-147

Beta Sources

Disc Sources

Promethium-147 incorporated in an enamel, mounted in a titanium capsule with 5µm titanium window, welded.

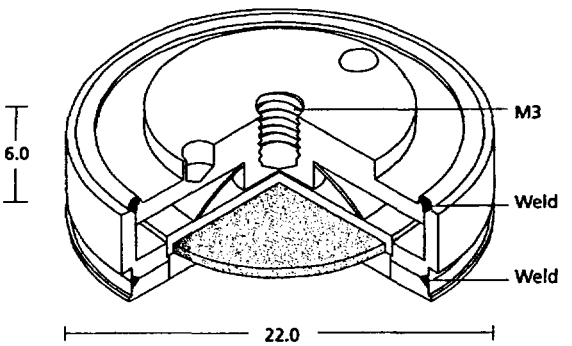
Nominal activity*		Active diameter	Overall diameter	Product code
GBq	mCi	mm	mm	
7.4	200	15.6	22	PHCB11997
18.5	500	15.6	22	PHCB11998

*Tolerance -10%, +25%

Recommended working life: 5 years

Quality Control
Wipe test I

VZ-2824



Safety performance testing

ANSI/ISO classification	US-Model number
C33222	PHC.C1

USA: AEA Technology QSA Inc, 40 North Avenue, Burlington, MA 01803, Phone No: +1 781 272 2000
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Quality control

Quality control of radiation can be divided into four main parts:

1. Checks made routinely during production

Quality Assurance
Radiation sources are manufactued in accordance with a strict quality assurance program, details of which can be obtained on request.

Leakage and contamination tests
Stringent tests for leakage are an essential feature of radioactive sources production. They are based on ISO 9978. Some standard methods used for testing radiation sources are listed below.

Wipe test I
The source is wiped with a swab or tissue, moistened with ethanol or water, the activity removed is measured.
Limit: 200Bq
(Limit USA: 5nCi)

Immersion test II
The source is immersed in a suitable liquid at 50°C for at least 4 hours and the activity removed is measured.
Limit: 200Bq
(Limit USA: 5nCi)

Bubble test III
The source is immersed in water or a suitable liquid and the pressure in the vessel reduced to 13kPa (100mm Hg). No bubbles must be observed.

Krypton emanation test V
The source is held under reduced pressure for 24 hours. The content of the chamber is analysed for Krypton-85 by scintillation counting.
Limit: 370Bq

Krypton emanation test VI
The source is held under reduced pressure for 24 hours. The content of the chamber is analysed for Krypton-85 by scintillation counting. The test is repeated after at least 7 days.
Limit: 1.85kBq

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Quality control

2. Special safety performance tests on prototypes

A radiation source must provide highest possible integrity together with minimum attenuation of the required radiation by the encapsulation materials. A compromise must sometimes be made, particularly for alpha, beta and low energy photon sources.

Safety must always be the prime consideration.
Standards for the testing of sealed radioactive sources have been specified by ISO.2919 and ISO.9978.

ISO.2919 'Sealed radioactive sources – Classification'
ISO.9978 'Sealed radioactive sources – leak test methods'.

This classification system is modeled on USA standard US ANSI N43.6-1997 which also gives a number of comparable leak test methods.

3. Measurements

Each source of batch of sources is checked to ensure that the strengths of the sources supplied are within the limits specified. Wherever possible the results of these checks are indicated on the test report. The methods of specifying the strengths of sources are discussed under the heading specification on page E1 and details are included in the appropriate section of this catalog.

4. Test reports

A test report is supplied with each source or batch of sources. Where appropriate the following information is given:

Product code
Product description
Capsule type
ISO classification
Special form certificate
Serial number of source
Measurement check
Leakage check
Contamination check

ISO.9001 International Quality Management System Standard

In addition to our routine quality control procedures, AEA Technology QSA is approved to the International Quality Management System Standard ISO 9001: 2000.

This Quality Management System is a formal system which defines Quality Policy, describes the necessary organization in place to carry out the policy, and describes the procedures in place which are necessary to carry out and maintain the system.

The System involves the thorough training of all staff, documentation of procedures, maintenance of records and the assessment and rectification of non-conformities.

Regular surveillance audits are made by Lloyd's Register Quality Assurance Ltd,,* to ensure that the high standards demanded by ISO.9001 are maintained by AEA Technology QSA to all stages of the source production process from establishing the source specifications, through design, manufacture, test and measurement to despatch and after sales service.

*Lloyd's Register Quality Assurance Ltd. (LRQA) is accredited by the National Accreditation Council for Certification Bodies.

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Source safety

1. Classification of sealed source performance

A radiation source must provide the highest possible integrity for its contents together with the minimum attenuation of the emitted radiation by the encapsulation materials which is consistent with safety and the intended use. However, safety must always be the prime consideration.

The International Organization for Standardization have issued a standard (ISO 2919:1999) which establishes a system of classification of sealed radioactive sources based on test performance. It also specifies production tests, marking and gives an example of a test report. Similar standards are ANSI/HPS N43.6-1997 published in the USA.

These standards, to quote from ISO2919, "...provides a set of tests by which the manufacturer of sealed radioactive sources can evaluate the safety of his products in use and by which the user of such sources can select types which are suitable for the required application, especially where the release of radioactive material with consequent exposure to ionizing radiation is concerned."

The suitability and safety of a source will depend on the intended application and the environment of use of which there will be a wide range. It is the customer's (users) responsibility to ensure the source and its specification are suitable and safe for his particular application and environment of use. This applies to standard products and especially to non-standard products or custom made designs. The information given here is intended for guidance. It is recommended that the standards should be consulted for detailed definitive information.

The standard tests for the classification of sealed source performance (ISO 2919) are given in Table 1. Examples of additional tests which may be required for specific applications are given in the appendix to ISO 2919.

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Source safety

Table 1. Classification of sealed source performance

Test	Class						
	1	2	3	4	5	6	X
Temperature	No test	-40°C (20min) +80°C (1h)	-40°C (20min) +180°C (1h)	-40°C (20min) + 400°C (1h) and thermal shock to 20°C	-40°C (20min) +600°C (1h) and thermal shock to 20°C	-40°C (20min) +800°C (1h) and thermal shock to 20°C	Special test
External pressure	No test	25kPa absolute to atmospheric	25kPa absolute to 2MPa absolute	25kPa absolute to 7MPa absolute	25kPa absolute to 70MPa absolute	25kPa absolute to 170MPa absolute	Special test
Impact	No test	50g from 1m or equivalent imparted energy	200g from 1m or equivalent imparted energy	2kg from 1m or equivalent imparted energy	5kg from 1m or equivalent imparted energy	20kg from 1m or equivalent imparted energy	Special test
Vibration	No test	3 times 10min 25 to 500Hz at 49m/s² ($5g_n$)[1]	3 times 10min 25 to 50Hz at 49m/s² ($5g_n$)[1] and 50 to 90Hz at 0.635mm amplitude peak to peak and 90 to 500Hz at 96m/s² ($5g_n$)[1]	3 times 30min 25 to 80Hz at 1.5mm amplitude peak to peak and 80 to 2000Hz at 196m/s² ($20g_n$)[1]	Not used	Not used	Special test
Puncture	No test	1g from 1m or equivalent imparted energy	10g from 1m or equivalent imparted energy	50g from 1m or equivalent imparted energy	300g from 1m or equivalent imparted energy	1kg from 1m or equivalent imparted energy	Special test

1) Acceleration maximum amptitude

Notes to table 1.

1. Details of the testing procedures are given in ISO.2919 and ANSI N43.6-1997. A further class X can be used where a special test procedure has been adopted.
2. External pressure
   100kPa=1 atmosphere (approximate)
3. Impact test
   The source, positioned on a steel anvil, is struck by a steel hammer of the required weight; the hammer has a flat stricking surface, 25mm diameter, with the edges rounded.
4. Puncture test
   The source, positioned on a hardened steel anvil, is struck by a hardened pin, 6mm long, 3mm diameter, with hemispherical end, fixed to a hammer of the required weight.

Each test can be applied in several degrees of severity which is expressed as a five digit code representing the class numbers which describe the performance for each of the tests. The digits are preceded by the letter C or E indication respectively whether the activity of the source is greater or lesser than a prescribed amount. The limits depend on the toxicity etc of the active components (See ISO 2919) Compliance with the tests is determined by the ability of sealed source to maintain its leak tightness. The leakage tests are defined in ISO 9978.

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Source safety

2. Performance requirements for Typical Uses

Typical uses and minimum performance requirements (ISO 2919) are given in Table 2.

Table 2 Sealed source classification (performance) requirements for typical usage

Sealed source usage		Sealed source class, depending on test				
		Temperature	Pressure	Impact	Vibration	Puncture
Radiography-Industrial	Sealed source	4	3	5	1	5
	Source to be used in device	4	3	3	1	3
Medical	Radiography	3	2	3	1	2
	Gamma teletherapy	5	3	5	2	4
	Brachytherapy (6)[1]	5	3	2	1	1
	Surface applicators[2]	4	3	3	1	2
Gamma gauges	Unprotected source	4	3	3	3	3
(medium and high energy)	Source in device	4	3	2	3	2
Beta gauges and sources for low-energy gamma gauges or x-ray fluorescence analysis[2]		3	3	2	2	2
Oil-well logging		5	6	5	2	2
Portable moisture and density gauge (including hand-held or dolly-transported)		4	3	3	3	3
General neutron source application (excluding reactor startup)		4	3	3	2	3
Calibration source activity >1 MBq		2	2	2	1	2
Gamma irradiation sources Category 1[2] [3], [5]		4	3	3	2	3
	Categories II,III and IV[3]	5	3	4	2	4
Ion generators[3]	Chromatography	3	2	2	1	1
	Static eliminators	2	2	2	2	2
	Smoke detectors[2]	3	2	2	2	2

1) Sources of this nature may be subject to severe deformation in use. Manufactures and users may wish to formulate additional or special test procedures.
2) Excluding gas-filled sources.
3) "Source in device" or a "source assembly" may be tested.

The requirements take into account normal usage but do not include exposure to fire, explosion or corrosion. The test specified do not cover all usage situations and where conditions do not match those specified in Table 2 appropriate tests on an individual basis may be required.

USA: AEA Technology QSA Inc, 40 North Avenue, Burlington, MA 01803, Phone No: +1 781 272 2000
Hong Kong: AEA Technology QSA, Room 3503, 35/F, China Resources Building,
26 Harbour Road, Wanchai, Phone No: +852 2596 7711
Germany: AEA Technology QSA GmbH, Gieselweg 1, 38110 Braunschweig, Phone No: +49 (0)5307 9320
France: AEA Technology QSA, 12 Avenue des Tropiques, Hightec Sud - Bâtiment B,
F91955 Courtaboeuf Cedex, Phone No: +33 164 86 22 21

Source safety

3. IAEA special form

Sealed sources which have passed the performance tests described in the reglations for the Safe Transport of Radioactive Material, 1996 Edition (Revised), International Atomic Energy Agency (IAEA), No.
TS-R-1 (ST-1,Revised) may be approved as Special Form Material by a National Competent Authority. Designation as Special Form allows an increase in the activity limits for shipment as a Type A package.

The Special Form Certificate (SFC) numbers are given against approved items in the catalog.

RECOMMENDED WORKING LIFE OF SEALED RADIATION SOURCES

The Recommended Working Life (RWL) is the maximum period within which AEA Technology QSA expects the source to meet it's design requirements under proper conditions of environment and usage. A Source should be replaced within the Recommended Working Life or a proper assessment should be made to verify its suitability for continued use.

AEA Technology QSA makes no warranties, expressed or implied, or guarantees as to how long any source can actually be safely used. Adverse environments, conditions, improper usage or materials combination in usage could effect the appearance and integrity of the source and it is the user's responsibility to carry out routine inspection and testing to determine when it should be replaced.

AEA Technology QSA will determine the RWL based on the construction of the source, application, test data and operational experience.

Issued by the AEA Technology QSA Board June 2003

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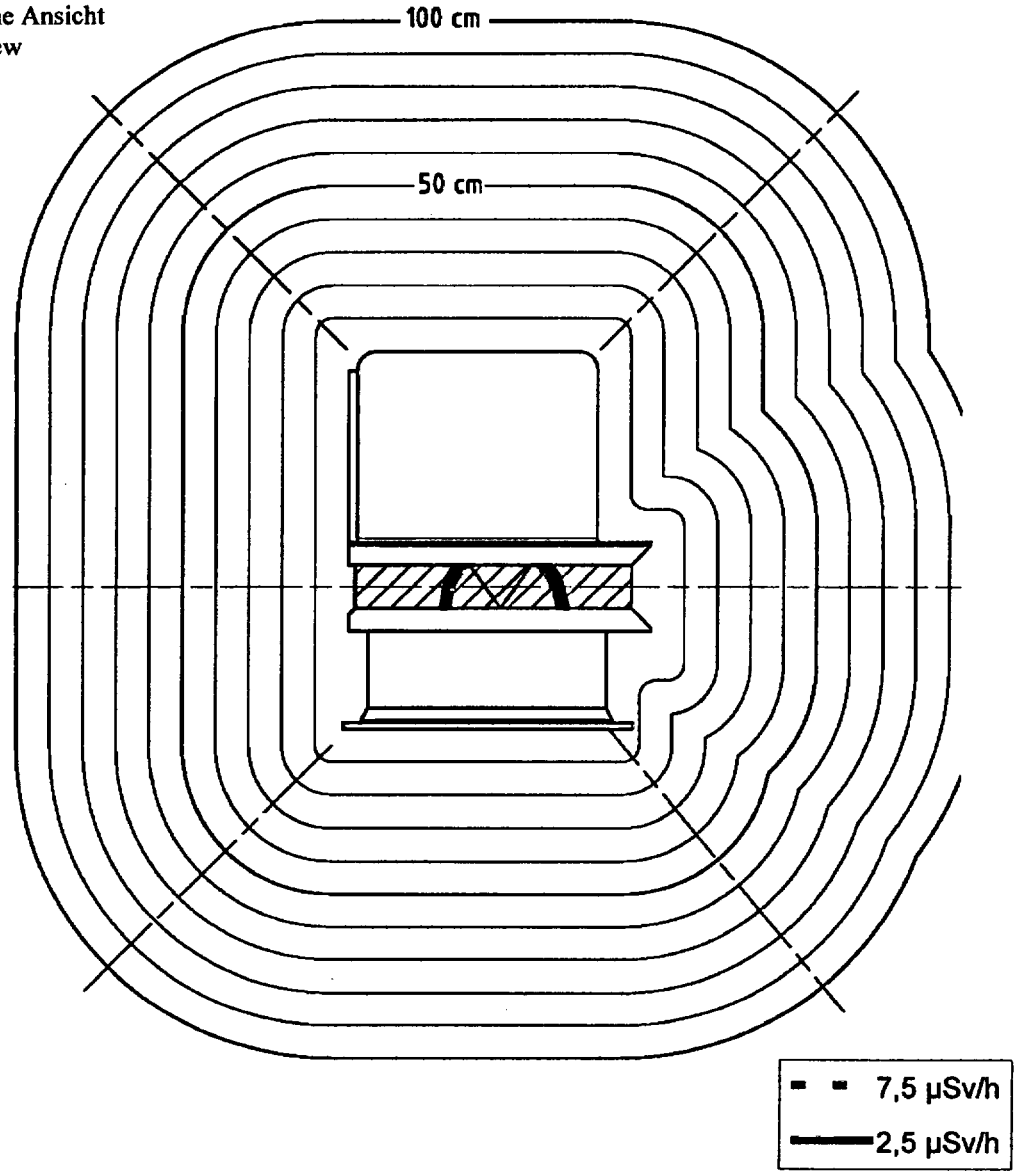
Isodosiskurven / isodose curves nach DIN 412-1

Strahler im *Messbetrieb* / source *unshielded*

Seitliche Ansicht
side view

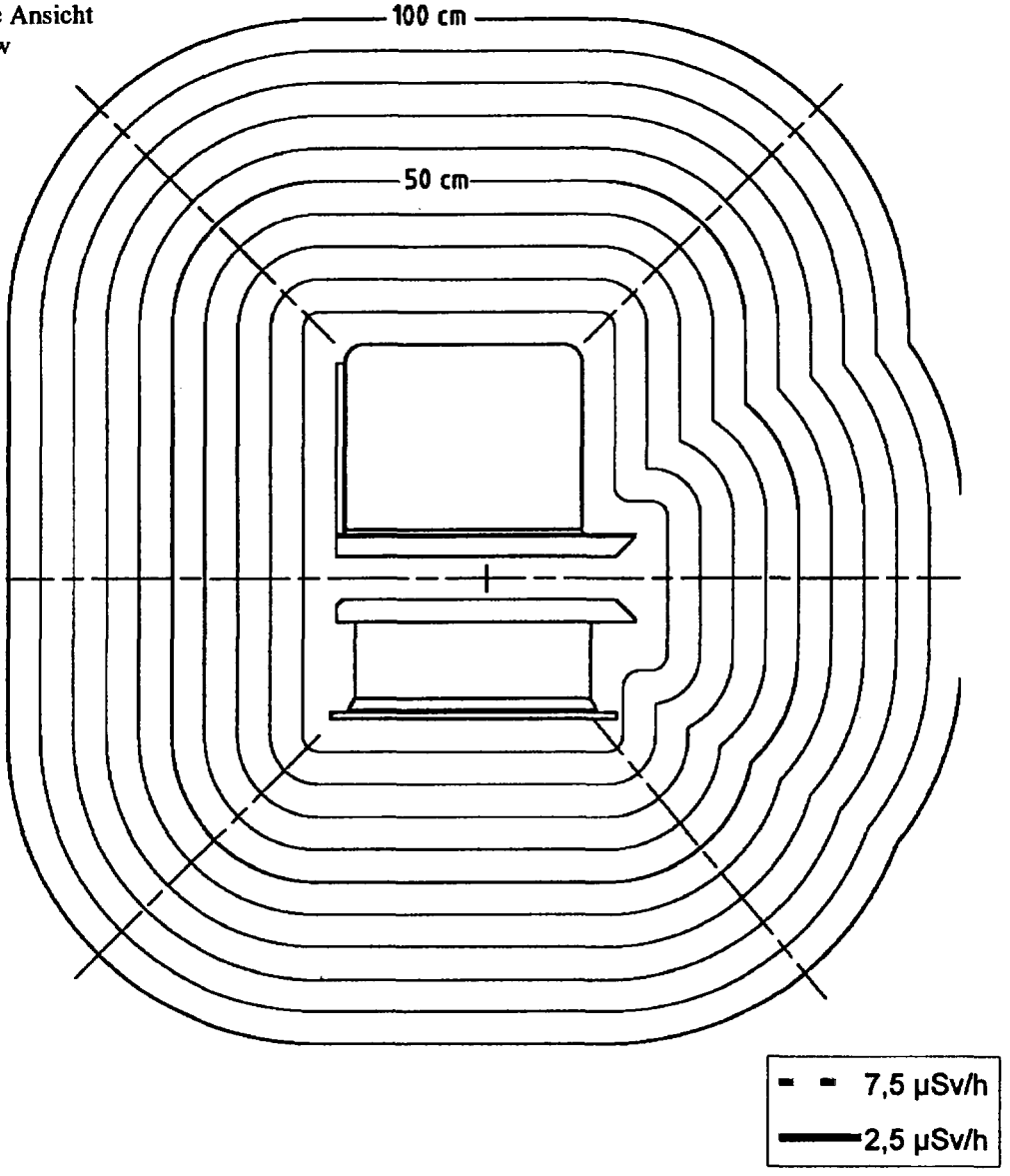


Modell: BC MK 1.0 device model	**Messspalt: 10 mm** measurement gap	**Strahlungsmessgerät: babyline 31** radiation gauge
Isotop: Pm147 isotope	**Kollimator: Rund** circular collimator	**Nr.: Pm147-1,85-10mm-simuliert; Bl. 1** number of drawing
Aktivität: 1,85 GBq activity		

Isodosiskurven / Isodose curves nach DIN 412-1

Strahler ***abgeschirmt / source shielded***

Seitliche Ansicht
side view

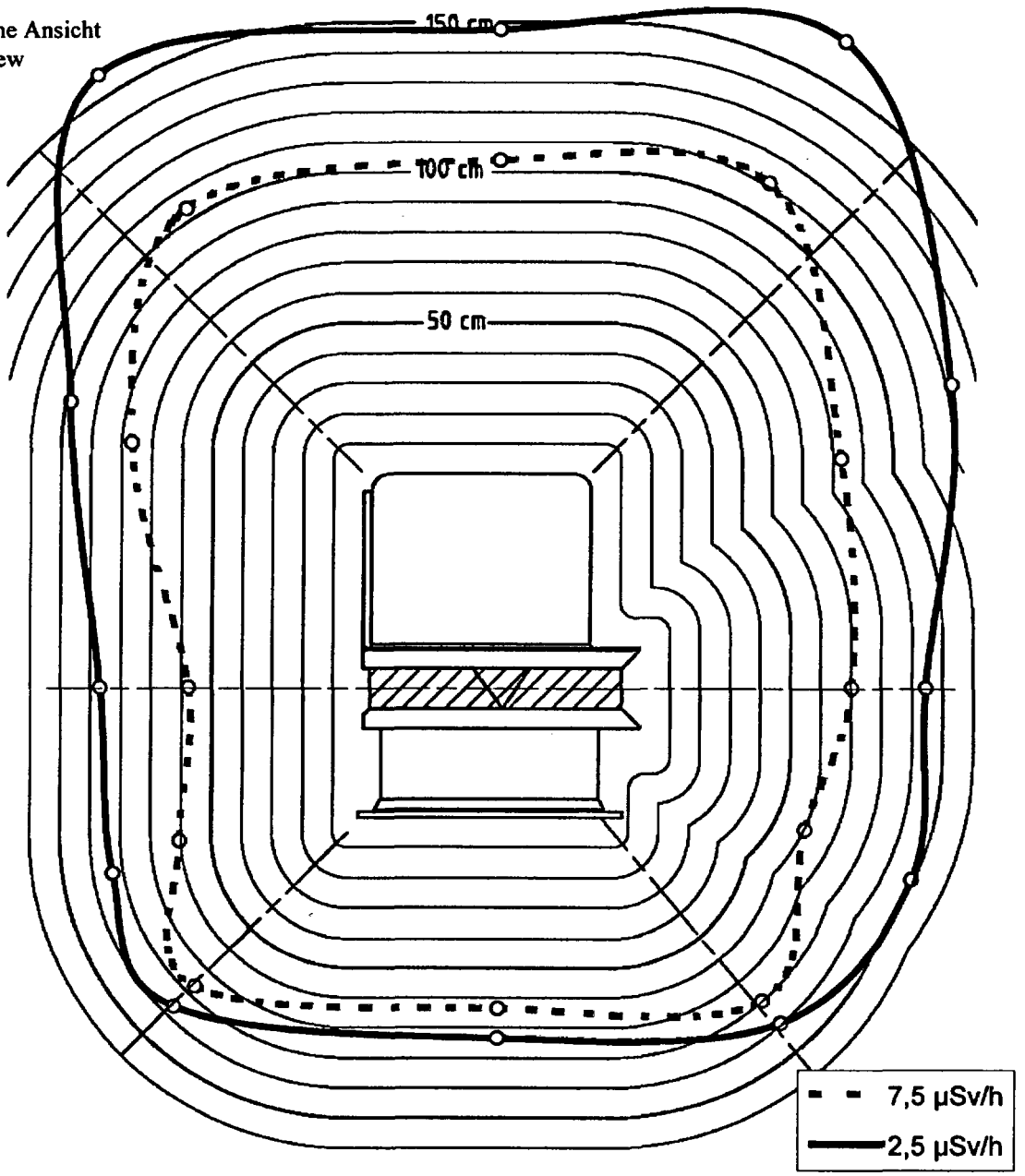


Modell: BC MK 1.0 device model	**Messspalt: 10 mm** measurement gap	**Strahlungsmessgerät: babyline 31** radiation gauge
Isotop: Pm147 isotope	**Kollimator: Rund** circular collimator	**Nr.: Pm147-1,85-10mm-simuliert; Bl. 2** number of drawing
Aktivität: 1,85 GBq activity		

Isodosiskurven / Isodose curves nach DIN 412-1

Strahler im *Messbetrieb* / source *unshielded*

Seitliche Ansicht
side view

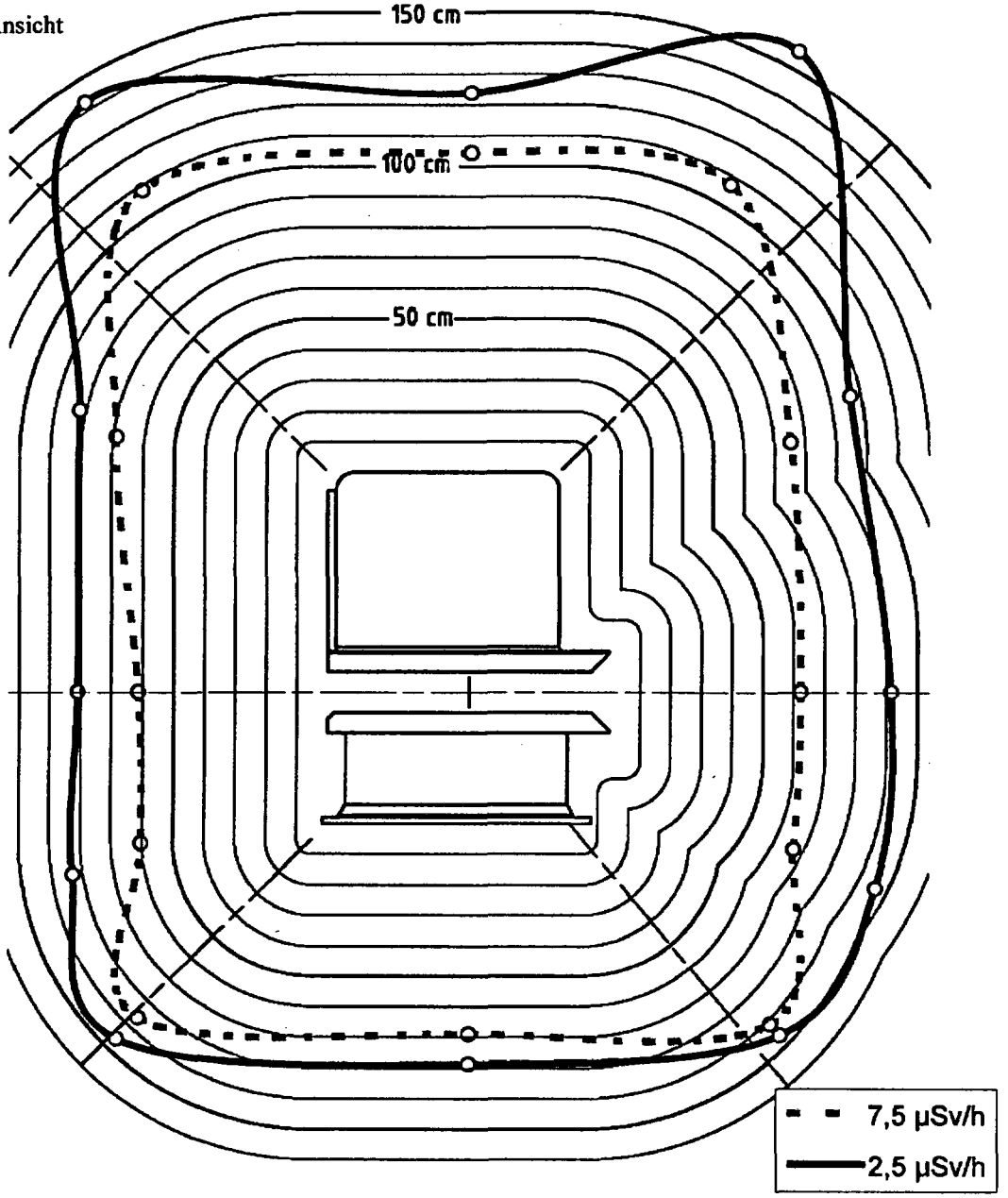


Modell: BC MK 1.0 device model	**Messspalt: 35 mm** measurement gap	**Strahlungsmessgerät: babyline 31** radiation gauge
Isotop: Sr90 isotope	**Kollimator: Schlitz 10 x 35 mm** slotted collimator	**Nr.: Sr90-1,85-35mm-simuliert; Bl. 1** number of drawing
Aktivität: 1,85 GBq activity		

Isodosiskurven / isodose curves nach DIN 412-1

Strahler ***abgeschirmt / source shielded***

Seitliche Ansicht
side view

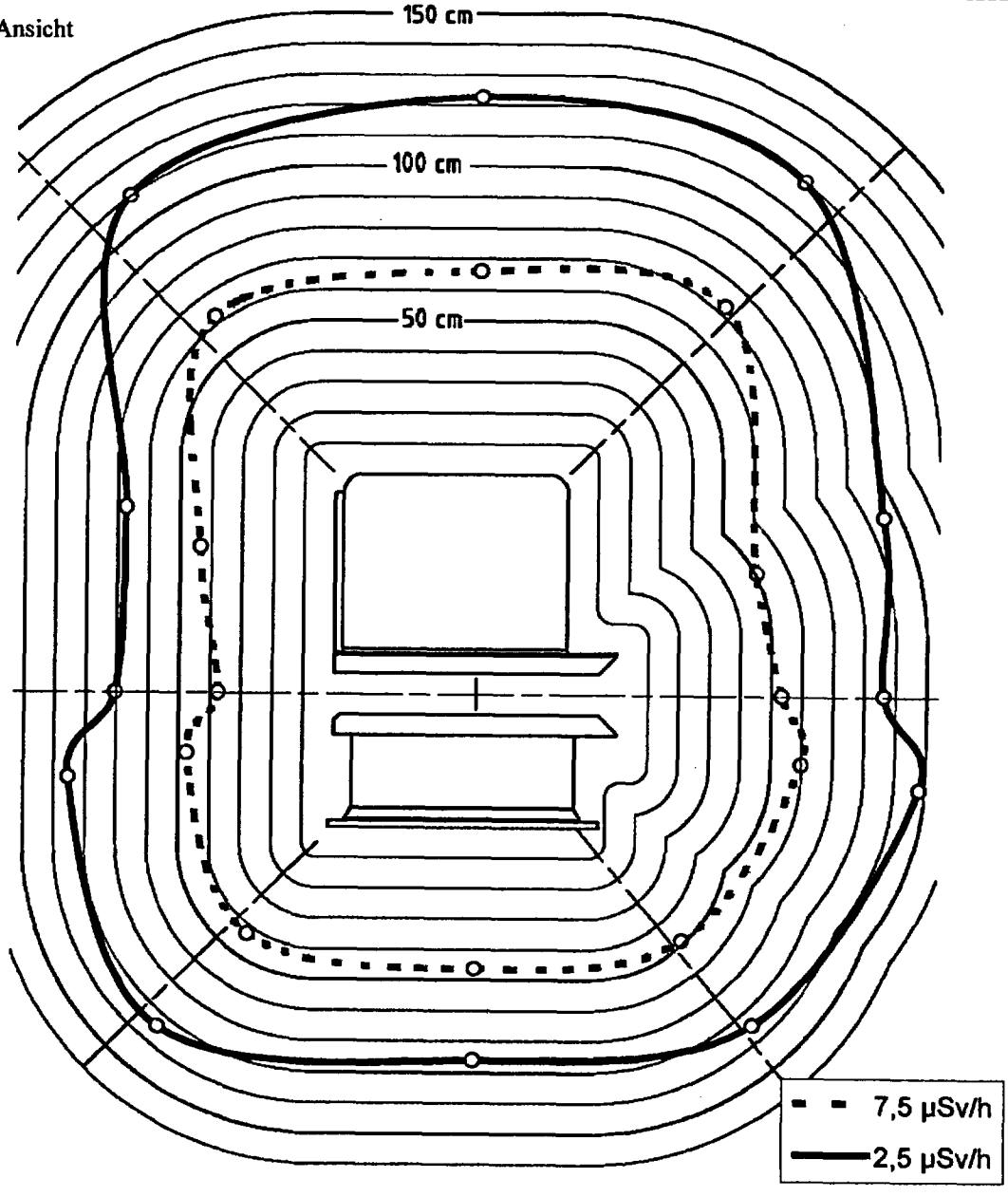


Modell: BC MK 1.0 device model	**Messspalt: 35 mm** measurement gap	**Strahlungsmessgerät: babyline 31** radiation gauge
Isotop: Sr90 isotope	**Kollimator: Schlitz 10 x 35 mm** slotted collimator	**Nr.: Sr90-1,85-35mm-simuliert; Bl. 2** number of drawing
Aktivität: 1,85 GBq activity		

Isodosiskurven / isodose curves nach DIN 412-1

Strahler ***abgeschirmt*** **/ source** ***shielded***

Seitliche Ansicht
side view

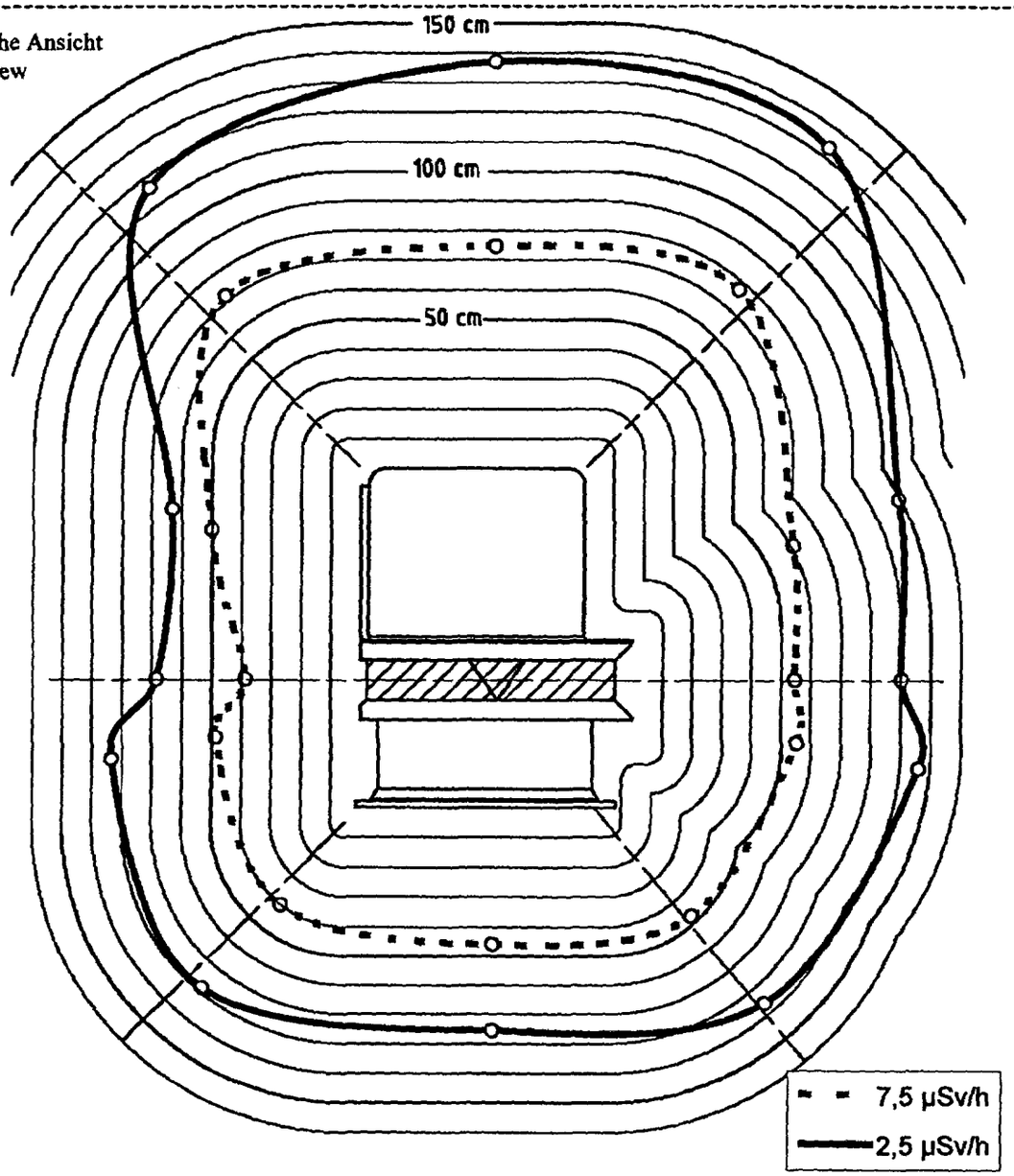


Modell: BC MK 1.0 device model	**Messspalt: 10 mm** measurement gap	**Strahlungsmessgerät: babyline 31** radiation gauge
Isotop: Kr85 isotope	**Kollimator: Schlitz 10 x 35 mm** slotted collimator	**Nr.: Kr85-18,5-10mm-simuliert; Bl. 2** number of drawing
Aktivität: 18,5 GBq activity		

Isodosiskurven / Isodose curves nach DIN 412-1

Strahler im *Messbetrieb* / source *unshielded*

Seitliche Ansicht
side view



Modell: BC MK 1.0 device model	**Messspalt: 10 mm** measurement gap	**Strahlungsmessgerät: babyline 31** radiation gauge
Isotop: Kr85 isotope	**Kollimator: Schlitz 10 x 35 mm** slotted collimator	**Nr.: Kr85-18,5-10mm-simuliert; Bl. 1** number of drawing
Aktivität: 18,5 GBq activity		